User Manual

Vanguard® Breast MRI Tabletop Coil
1.5T, 63.86 MHz

For use with GE Signa™ HDx and HDxt 1.5T Systems

SMI-0517 Rev. 101

Sentinelle Medical
555 Richmond St. W.
Suite 800, P.O. Box 301
Toronto, ON, Canada, M5V 3B1
Phone: (North America) 1-866-735-3744
(International) 1-416-366-4994
Fax: 1-647-258-0299
www.hologic.com

CE 0413

EC REP
EMERGO EUROPE
(+31) 70 345 8570

Emergo Europe
Molenstraat 15
2513 BH, The Hague
The Netherlands
Phone: +31 70 345 8570
Fax: +31 70 346 7299

Sentinelle Medical, a Division of Hologic
555 Richmond St. W. Suite 800, P.O. Box 301
Toronto, Ontario, Canada M5V 3B1

Phone (including Technical Support): (North America) 1-866-735-3744
(International) 1-416-366-4994

Fax: 1-647-258-0299

Email: service@hologic.com

Service Hours: 8:00am - 5:00pm Eastern Standard Time (EST) Monday-Friday

www.sentinellemedical.com

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Preface

Regulatory Notification Information

CAUTION

Federal Law restricts this device to sale by or on the order of a physician.

The Vanguard must be installed and put into service according to the EMC information provided in this document. The Vanguard should be used only in a shielded location.

Portable and mobile RF communications equipment can affect the Vanguard.

Using accessories, cables and transducers other than those designed for the Vanguard may significantly degrade electromagnetic emissions and immunity performance. Do not use accessories, transducers and cables other than those specified in this manual.

About This Guide

This manual describes the functions, features, use, safety precautions, and maintenance for the Sentinelle Breast MRI Tabletop with 2/4/8-Channel Coil Array for GE Signa™ 1.5T, collectively referred to in this guide as the Vanguard. To use the Vanguard safely and effectively, it is essential that you review and familiarize yourself with this manual in its entirety before using the system.

The Vanguard is also available in a 4-channel configuration or an 8-channel Imaging-only configuration.

For an imaging-only configuration, sections that involve intervention or biopsy related items are not applicable.

NOTE: To upgrade to a complete system, contact your Sentinelle Medical sales representative.

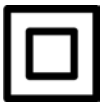
The graphics, figures, and medical images used in this manual are examples only. The display and design may vary on your system.

NOTE: Biopsy grids are not included with the GE catalog offering. These products can only be ordered directly from Sentinelle Medical.

Symbols and Safety Notices

The following symbols are used on Sentinelle Medical products to highlight information which, if not correctly followed, will directly impact patient and/or operator safety.

Table 1: Packaging and Safety Symbols

Safety Notice	Meaning
 DANGER	A red DANGER symbol is used to identify conditions or actions for which a specific hazard is known to exist. These conditions or actions will cause severe personal injury, death or substantial property damage if the instructions are not followed.
 WARNING	An orange WARNING symbol is used to identify conditions or actions for which a specific hazard is known to exist. These conditions or actions may cause severe personal injury or substantial property damage if the instructions are not followed.
 CAUTION	A yellow CAUTION symbol is used to identify conditions or actions for which a potential hazard may exist. These conditions or actions may cause minor personal injury or property damage if the instructions are not followed.
	IEC 60601 Type BF (body field) Applied Part.
	Class II (double-insulated) electrical equipment.
	Electrostatic Discharge (ESD) sensitivity.
	Follow instructions for use.
	Manufacturer of the device.
	NRTL (Nationally Recognized Testing Laboratories) safety testing and compliance.
 0413	Conformity with the essential requirements set out in the European Directives.

Safety Notice	Meaning
EC REP EMERGO EUROPE (+31) 70 345 8570	Authorized representative for Europe.
	Range of acceptable temperature conditions for shipping and storage.
	Acceptable range of relative humidity for shipping and storage.
	Acceptable range of atmospheric pressure for shipping and storage.
	Do not cross or loop cables and/or ECG leads; arcing and patient burns can result.
	Ensure cables or body parts are not pinched during patient support travel into or out of the scanner.
	No part of the Vanguard shall be disposed of in land fill. Return the device to Sentinelle Medical for disposal.
	Locked.
	Unlocked.
L	Left.
M	Medial.
R	Right.

Other Manual Conventions

The following styles are used throughout this manual.

- *A NOTE provides additional helpful information. It may emphasize information regarding special tools or techniques, items to check before proceeding, or factors to consider about a concept or task. Notes are always italicized.*
- Information in **Bold Sans-serif** type indicates scanner software text as it appears on the screen.

Patient and System Safety Warnings

The following general warning statements apply to scanning with this system in a magnetic resonance (MR) scanner. For additional safety information, review the warnings and safety standards in your MR system documentation.

Table 2: General Warning Statements

Safety Notice	Meaning
	Patients must not form a loop with any body parts while scanning. For example, they cannot touch any part of the right hand or arm to any part of the left hand or arm. This could cause a burn at the point of contact. Use pads to prevent any part of the patient's body from touching metal on the patient table. Educate the patient accordingly and check the patient's position immediately before the scan.
 **WARNING**	This coil system is only compatible with GE Signa™ 1.5T Scanners. The system is compatible with scanner software Version 23.0_V01 or later.
	Remove unused or improperly connected coils, cables, and gating leads from the MR scanner before performing a scan. Cables can become hot if they are left on the patient table when they are not connected to the scanner.
	Ensure the patient is not wearing damp clothing. This may interfere with proper operation of the system.
	All clothing containing metallic objects must be removed from the patient prior to exam.
	The use of medicinal products in transdermal patches may cause burns to underlying skin. All transdermal patches must be removed and the skin thoroughly cleaned prior to using the system as per your institution's MRI safety protocol.
	Check that the cable or lead(s) do not touch the sides of the MR scanner.

Safety Notice	Meaning
 WARNING	Exposure of the patient to radio frequency magnetic fields may increase the potential for local excessive heating of the patient. Immediately stop the MR scan acquisition if the patient complains of a tingling and/or heating sensation.
	All personnel using the Vanguard must be trained by an MRI technician training program accredited in the region where the device is being used. All personnel using the Vanguard must receive instruction in the proper connection and handling of the system and should be familiar with this User Manual.
	Auxiliary equipment (such as gating equipment, vital sign monitoring systems and RF coils) that has not been specifically tested and approved for use in an MR environment may result in burns or other injuries to the patient. This equipment may also interfere with the proper operation of this system.
	Coils are not suitable for use in the presence of flammable anaesthetics in combination with air, oxygen or nitrous oxide.
	Service personnel must have specialized training to ensure the safe operating condition of the coil and table system. Only properly trained and qualified personnel are authorized to service any components.
	The patient's body and extremities must not contact the inner surface of the MR bore. Burning may occur.
	Patients that are sedated, unconscious or are experiencing a loss of feeling in any body part should not be scanned. These patients would not be able to alert the operator as to excessive heating and associated tissue damage.
	Before using the Vanguard, check to ensure there is no external damage. Do not use a coil if the housing or cable is broken. Do not use coils, cables, or gating leads with exposed metal surfaces or abraded insulation.
	No modifications to the system are allowed. Further, any modification must be completed by trained Sentinelle Medical service personnel only as changes to the system may impact safety of the system.
 CAUTION	Ensure the Vanguard cable is located centrally in the scanner. Do not run the Vanguard cable along the edge of the bore.

Safety Notice	Meaning
 CAUTION	Position the patient and the coils and cable as prescribed in this User Manual.
	Ensure that the coil cable does not directly contact any part of the patient.
	Ensure the Vanguard Cable is not connected to the LPCA when lowering the scanner table.
	The Vanguard cable **must** be covered with the body pad before operation.
	To avoid tipping, use the Velcro straps to secure the Vanguard.
	Keep limbs away from the gap between the Vanguard and the scanner while raising and lowering the MR patient table.
	Do not reach under any of the guards while the MR patient table is being raised and lowered.
	Ensure the patient's feet do not overhang the end of the patient table while docking to the scanner.
	To avoid possible patient injury, do not use the automatic button to advance the patient into the scanner. Use the manual advance button and watch for potential contact of the patient with the bore as they advance into the scanner.
	Avoid using the Vanguard adjacent to or stacked with other equipment. If this is not avoidable, observe the equipment to verify that it operates normally.
	Do not cross or loop cables and/or ECG leads; this may result in arcing and patient burns.

Contacting Sentinelle Medical

Use the following information to contact Sentinelle Medical to report an incident or for technical support:

Phone (Including Technical Support): 1-866-735-3744 (North America)
1-416-366-4994 (International)

Fax: 1-647-258-0299

Email: service@hologic.com

Service hours are 8:00am - 5:00pm Eastern Standard Time (EST), Monday-Friday.

Reporting Incidents

Contact Sentinelle Medical immediately to report any incident and/or injury to a patient, operator or maintenance employee that occurred as a result of using the Vanguard.

If an accident occurs as a result of using the Vanguard, do not operate the equipment until an authorized investigation has been conducted.

For contact information, see Contacting Sentinelle Medical above.

Electrostatic Discharge (ESD) Safety

Do not touch the pins of connectors identified with the ESD warning symbol.

Do not use these connectors without taking ESD precautions. This includes:

- methods to prevent electrostatic charge build-up (for example, air conditioning, humidification, conductive floor coverings, non-synthetic clothing),
- discharging your body to earth or a large metal object,
- grounding yourself by means of a wrist strap to earth.

Electromagnetic Environment Information

This equipment receives RF electromagnetic energy. The system operates at a frequency of 63.86 MHz, over a bandwidth of 128 kHz. Other equipment may interfere with the Vanguard even if it complies with CISPR emission requirements.

The Vanguard must be used in the electromagnetic environment described below.

Table 3: Electromagnetic Environment (Emissions)

Emissions test	Classification	Electromagnetic Environment Guidance
RF emissions CISPR 11	Group 2	The Vanguard must receive electromagnetic energy to perform its intended function. Nearby electronic equipment may be affected.
RF emissions CISPR 11	Class A	The Vanguard must be used only in a shielded location with a minimum RF shielding effectiveness and, for each cable that exits the shielded location, a minimum RF filter attenuation of 20 dB over a minimum frequency range of 30 MHz to 300 MHz.
Harmonic emissions IEC 61000-3-2	Not Applicable	
Voltage fluctuations/flicker emissions IEC 61000-3-3	Not Applicable	
NOTE: It is essential that the actual RF shielding effectiveness and filter attenuation of the shielded location be verified to ensure that they meet or exceed the specified minimum values.		

Table 4: Electromagnetic Environment (Immunity)

Immunity test	IEC 60601 test level	Classification level	Electromagnetic Environment Guidance
Electrostatic discharge (ESD) IEC 61000-4-2	±6 kV contact ±8 kV air	±6 kV contact ±8 kV air	Floors should be wood, concrete or ceramic tile. If floors are covered with synthetic material, the relative humidity should be at least 30%.
Electrical fast transient/burst IEC 61000-4-4	±2 kV for power supply lines ±1 kV for input/output lines	Not Applicable	Mains power quality should be that of a typical commercial or hospital environment.
Surge IEC 61000-4-5	±1 kV line(s) to line(s) ±2 kV line(s) to earth	Not Applicable	Mains power quality should be that of a typical commercial or hospital environment.
Voltage dips, short interruptions and voltage variations on power supply input lines IEC 61000-4-11 UT = 230 Vac	<5% UT (>95% dip in UT) for 0,5 cycle 40% UT (60% dip in UT) for 5 cycles 70% UT (30% dip in UT) for 25 cycles <5% UT (>95% dip in UT) for 5 sec	Not Applicable	Mains power quality should be that of a typical commercial or hospital environment. If the Vanguard must operate continuously during power mains interruptions, it must be powered from an uninterruptible power supply or a battery.
Power frequency (50 Hz) magnetic field IEC 61000-4-8	3 A/m	Not Applicable	Power frequency magnetic fields should be at levels characteristic of a typical location in a typical commercial or hospital environment.

Table 5: Electromagnetic Environment (Conducted/Radiated)

Immunity test	IEC 60601 test level	Classification level	Electromagnetic Environment Guidance
Conducted RF IEC 61000-4-6	3 Vrms 150 kHz to 80 MHz	3 Vrms	The Vanguard must be used only in a shielded location with a minimum RF shielding effectiveness and, for each cable that enters the shielded location, a minimum RF filter attenuation of 20 dB from a minimum frequency range of 30 MHz to 300 MHz (See the previous table.) Field strengths outside the shielded location from fixed RF transmitters, as determined by an electromagnetic site survey, should be less than 3 V/m.
Radiated RF IEC 61000-4-3	3 V/m 80 MHz to 2,5 GHz	3 V/m	Interference may occur in the vicinity of known RF transmitting devices and equipment marked with the following symbol: 
NOTE: These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.			
Field strengths from fixed transmitters, such as base stations for radio (cellular/cordless) telephones and land mobile radios, amateur radio, AM and FM radio broadcast and TV broadcast cannot be predicted theoretically with accuracy. An electromagnetic site survey will assess the electromagnetic environment due to fixed RF transmitters. If the measured field strength in the location where equipment is used exceeds the applicable RF compliance levels, the equipment should be observed to verify normal operation. If abnormal performance is observed, you may need to re-orient or relocate the equipment or use a location with higher RF shielding effectiveness and filter attenuation.			

Chapter 1

Chapter 1 The Vanguard System

The Vanguard is a dedicated breast MR imaging coil and interventional system. It consists of a patient support with breast immobilization system and an attached 2/4-channel or 8-channel coil system.

For clinical imaging, clear immobilization plates in the immobilization frames help minimize motion artifacts due to patient motion during scanning.

For interventional procedures, sterile, single-use disposable biopsy grids* are used to both immobilize the breast and provide access windows for biopsy needle guidance.

** Biopsy grids are not included with the GE catalog offering. These products can only be ordered directly from Sentinelle Medical.*

System Classification

The Vanguard System is classified according to IEC 60601-1 as follows:

- Type BF Applied Part
- Degree of Protection against Ingress of Water: IPX0
- Equipment not suitable for use in the presence of a Flammable Anaesthetic mixture with Air or Oxygen or Nitrous Oxide
- Mode of Operation: Continuous operation

Indications and Contraindications for Use

Indications for Use

The Vanguard is designed to provide magnetic resonance (MR) images of breast anatomy when used in conjunction with an MR scanner. The images can be interpreted by a trained physician. When used with a single-use sterile biopsy grid*, the Vanguard permits access to the breast anatomy for biopsy and localization procedures that can be performed by a trained physician.

** Biopsy grids are not included with the GE catalog offering. These products can only be ordered directly from Sentinelle Medical.*

Contraindications for Use

The following contraindications for use relate to the strong magnetic field of the MR scanner:

Table 6: Contraindication Safety Notices

 **DANGER**	Scanning is contraindicated for patients who have electrically, magnetically or mechanically activated implants such as cardiac pacemakers, or who rely on electrically, magnetically or mechanically activated external life support systems. The magnetic and electromagnetic fields produced by the MR scanner and coil may interfere with the operations of these devices. Scanning patients with intracranial aneurysm clips is contraindicated unless the physician is certain that the clip is not magnetically active.
 **CAUTION**	Examination by MR equipment requires particular caution in the following cases: • patients with implanted surgical clips (haemostatic clips) or other ferromagnetic materials, which the magnetic field may dislodge • patients with certain types of intrauterine devices (IUDs) • patients engaged in occupations or activities which may cause accidental implantation of ferromagnetic materials, or who may have embedded metal fragments from military activities • patients with permanent (tattoo) eye-liner or with facial make-up (severe eyelid irritation has been reported) • patients with compromised thermoregulatory systems • patients with metal implants (these may cause artifacts in the diagnostic images) • patients with implanted prosthetic heart valves • patients who are pregnant

See also Safety Notices for Interventional Procedures on page 53.

Specifications

Coil System Specifications

- Field Strength: 1.5T
- Frequency: 63.86MHz

Patient Support Specifications:

- Maximum patient weight: 158.8kg (350lb)
- Maximum load on each Patient Support arch: 45.4kg (100lb)

For details on correct patient positioning to support the maximum patient weights listed, please refer to the Patient Positioning and Preparation Guidelines Chapter, beginning on page 43.

Compatible Biopsy Devices

The following MRI-compatible biopsy devices are mechanically compatible with the Vanguard.

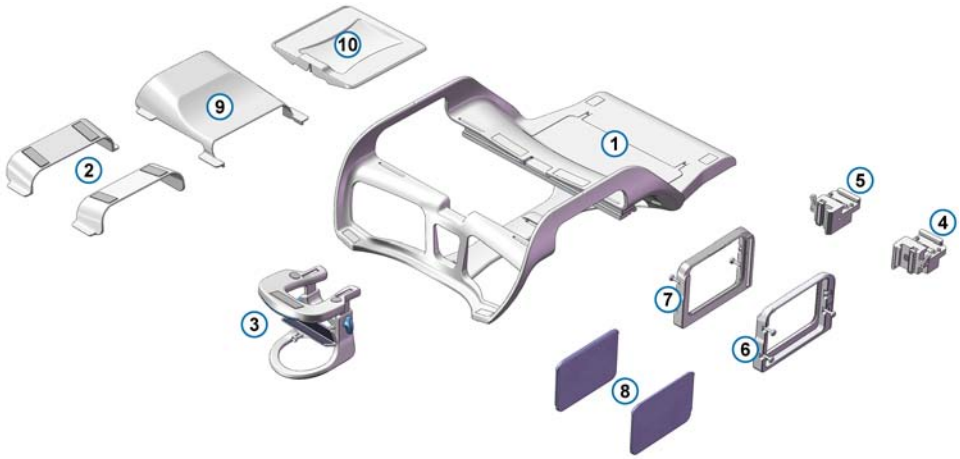
- Suros ATEC
- Suros ATEC Petite
- SenoRx EnCor 7G
- SenoRx EnCor 10G
- SenoRx EnCor 14G
- Mammotome J&J 8G 115mm and 145mm
- Mammotome J&J 11G 115mm and 145mm
- Bard VACORA 10G 118mm and 140mm
- Bard VACORA 14G 116mm and 138mm
- WireLoc 14G and 18G*

** Any gauge that fits in the needle block is compatible, however only 14G and 18G are options in the Sentinelle Medical Aegis software product.*

NOTE: Biopsy grids and biopsy devices are not included with the GE catalog offering.

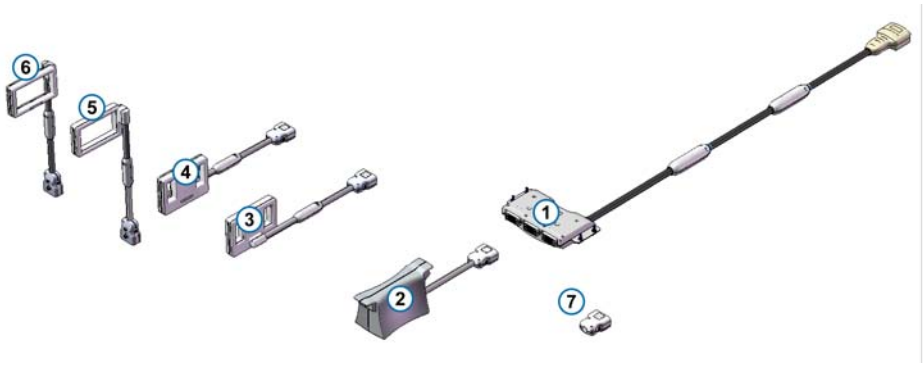
System Components

The following figures show the Vanguard components in each type of system.



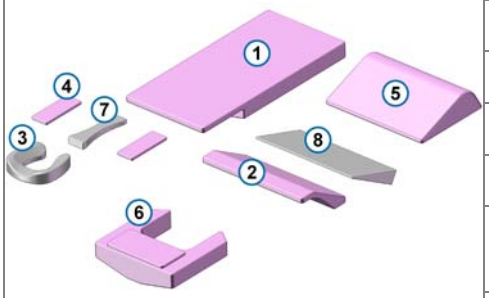
#	Component	Qty	Complete System	8-Ch Imaging-only	4-Ch Option
1	Patient Support	1	✓	✓	✓
2	Shoulder Support with Velcro kit	2	✓	✓	✓
3	Headrest	1	✓	✓	✓
4	Left Horizontal Slider Assembly	1	✓	✓	✓
5	Right Horizontal Slider Assembly	2	✓	✓	✓
6	Left Immobilization Frame	1	✓	✓	✓
7	Right Immobilization Frame	1	✓	✓	✓
8	Immobilization Plate	2	✓	✓	✓
9	Contralateral Breast Support	1	✓		✓
10	Catchment Tray	1	✓		✓
11	Velcro Straps (not shown)	2	✓	✓	✓
12	Imaging Phantom (not shown)	2	✓	✓	✓

Figure 1: Patient Support and Accessory Components



#	Component	Qty	Complete System	8-Ch Imaging-only	4-Ch Option
1	Vanguard Breast Cable System	1	✓	✓	✓
2	Medial Array Coil	1	✓	✓	✓
3	Left Lateral Array Coil	1	✓	✓	
4	Right Lateral Array Coil	1	✓	✓	
5	Left Single Loop Coil	1	✓		✓
6	Right Single Loop Coil	1	✓		✓
7	Medial Plug	1	✓		✓

Figure 2: RF Components



#	Component
1	Body Pad
2	Body Wedge Pad
3	Headrest Pad
4	Shoulder Support Pads
5	Foot Rest Pad
6	Front Pad with Hand Separation Flap
7	Medial Array Pad
8	Hip Wedge Pad

Figure 3: Padding Components

NOTE: For instructions on how to arrange the padding for optimal patient comfort, see the Patient Positioning and Preparation Guidelines Chapter, beginning on page 43.

Patient Support Setup

The Vanguard should be placed feet first on the GE Signa patient table toward the bore so the Vanguard Cable, located at the foot end of the patient support, can be securely plugged into the scanner.

Figure 4: Patient Support on Signa™ Patient Table

Anti-Tip Velcro straps

To prevent the patient support from tipping, ensure the anti-tip Velcro straps are properly attached before allowing a patient to mount the patient support. Insert a Velcro strap into the slots on each side of the GE table, then slide and fasten them to the Vanguard.

Figure 5: Securing the Patient Support with the Anti-Tip Velcro straps

Catchment Tray

For unilateral and bilateral interventional procedures the catchment tray must be in place. This is a safety mechanism ensuring the MR guided needle device can

safely be directed into the breast tissue. During interventional procedures, you may want to drape the catchment tray with an absorbent pad to catch any spills that happen during the procedure.

Figure 6: Inserting the Catchment Tray

Using the Headrest

The headrest cushion is attached to a movable stand. To adjust the height, unlock the headrest by turning the knob on the side, as shown in the figure below on the left. Adjust the angle of the headrest by pulling out the handle at the front as shown in the figure below on the right.

A mirror is available to allow the patient to see outside the bore during scanning. Adjust the mirror position after the height and angle of the headrest have been adjusted for comfort.

If the headrest is in its lowest height and angle position, remove the mirror by pulling it directly away from the headrest to avoid interference.

Figure 7: Adjusting Headrest Height

Figure 8: Adjusting Headrest Angle

The Coils

The Vanguard coils consist of an 8-channel configuration, and an interchangeable 4-channel and 2-channel configuration. The coils can be changed or reconfigured, depending upon the particular imaging requirement.

An Imaging-only option comprises an 8-channel coil set only. A 4-channel option comprises 4-channel and 2-channel coils for both imaging and interventional work.

NOTE: To upgrade to a complete system, contact your Sentinelle Medical sales representative.

Coil Naming

For consistency and ease of use, this manual uses simplified coil names, not the coil names as they are listed on the coil labels. The following table maps the technical name of each coil as it appears on the coil label to the common name for the coil used in this manual.

Table 7: Coil Name Cross-reference

Coil Label Name	Coil Common Name
Lateral Array Coil Right	Right Lateral Array Coil
Lateral Array Coil Left	Left Lateral Array Coil
Medial Array Coil	Medial Array Coil
Lateral Single Loop Coil Left	Left Single Loop Coil
Lateral Single Loop Coil Right	Right Single Loop Coil

Coil File Software Installation

The Sentinelle coil file Version 23.0_V01 or later must be installed by a trained Sentinelle Medical or GE Medical service representative.

Coil Configurations

The scanner will automatically select the appropriate configuration when a valid coil combination is connected. The following table describes the various coil arrangements, available for specific procedural requirements.

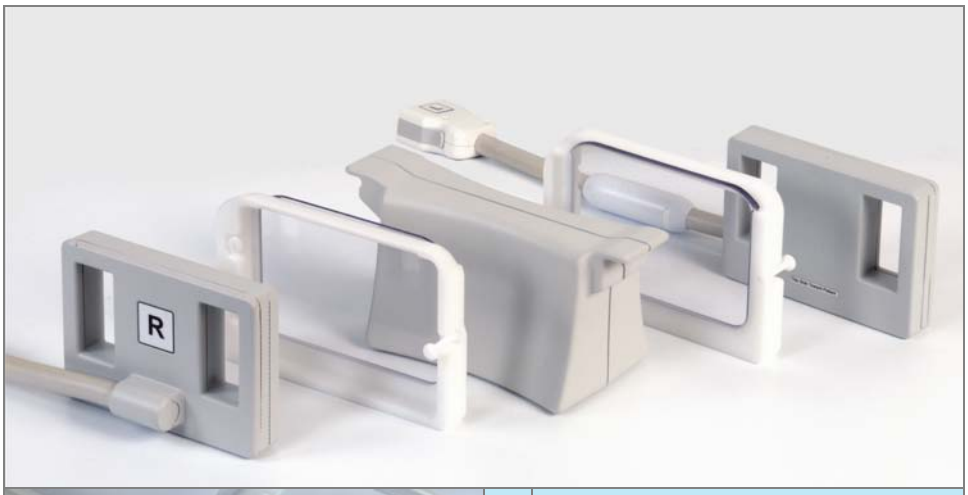
Table 8: Available Coil Configurations

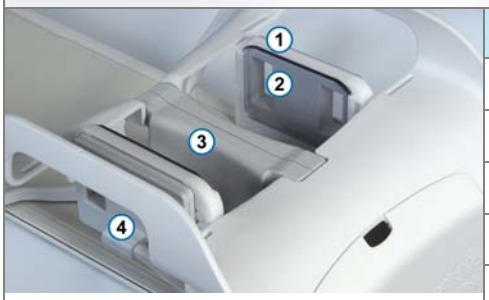
Procedure	Receptacle			Coil Configuration on MRI	Complete System	8-Ch Imaging-Only	4-Ch System
	L	M	R				
8-Ch Bilateral Imaging	Left Lateral Array Coil	Medial Array Coil	Right Lateral Array Coil	Select coil **8ch Bilat HD Breast Array by Sentinelle** Use **8Brst BL TT SMI**	✓	✓	

Procedure	Receptacle			Coil Configuration on MRI	Complete System	8-Ch Imaging-Only	4-Ch System
	L	M	R				
8-Ch Unilateral Imaging	Left Lateral Array Coil	Medial Array Coil	Right Lateral Array Coil	Select coil **8ch Bilat HD Breast Array by Sentinelle** Left Breast use: **8Brst Lt TT SMI** Right Breast use: **8Brst Rt TT SMI**	✓	✓	
4-Ch Bilateral Imaging/ Intervention	Left Single Loop Coil	Medial Array Coil	Right Single Loop Coil	Select coil **4ch Bilat Biopsy HD Breast Array by Sentinelle** Use **4Brst BLI TT SMI**	✓		✓
Unilateral Intervention	Left Single Loop Coil	Medial Plug	Right Single Loop Coil	Select coil **2ch Unilat Biopsy HD Breast Array by Sentinelle** Use **2Brst Int TT SMI**	✓		✓

Coil Setup

The following figures show the Vanguard's general set up for bilateral breast imaging, unilateral interventional and bilateral interventional procedures.

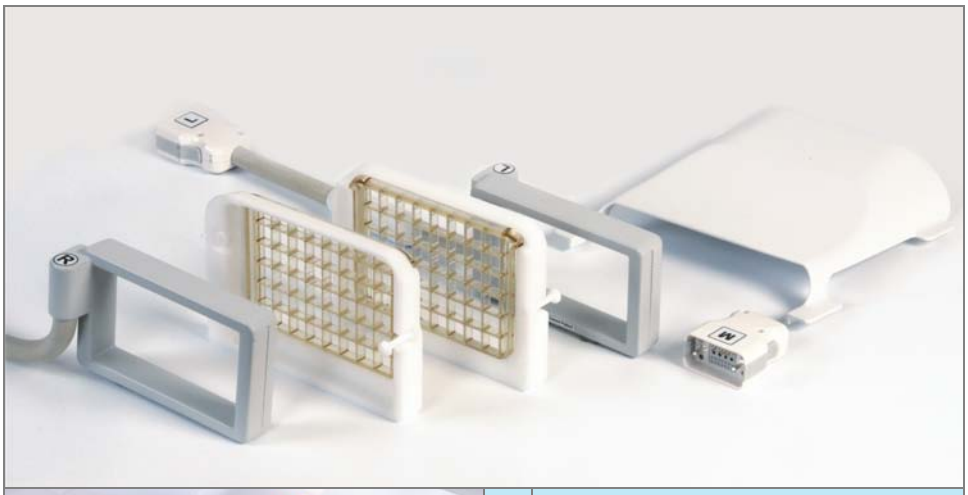


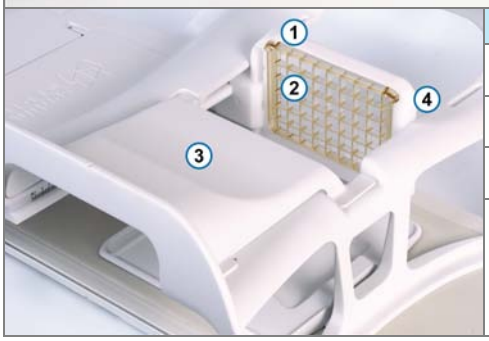


#	Component
1	Right Lateral Array Coil
2	Clear Immobilization Plate
3	Medial Array Coil
4	Immobilization Frame
5	Left Lateral Array Coil

Figure 9: Bilateral Imaging Components and Setup (Without Padding)

NOTE: Use single loop coils in place of lateral array coils for a 4-channel system.



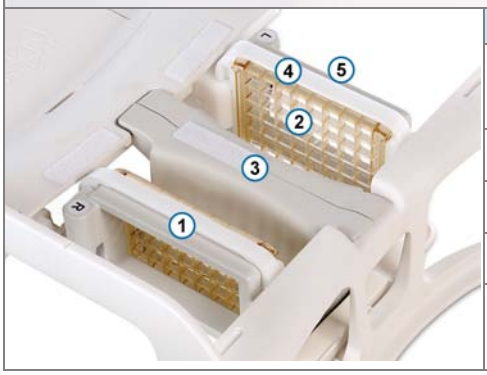


#	Component
1	Immobilization Frame
2	Biopsy Grid
3	Contralateral Breast Support
4	Place Right and Left Single Loop Coils in Immobilization Frames

Figure 10: Unilateral Intervention Setup and Components (Without Padding)

About the Contralateral Breast Support

The contralateral breast support holds the contralateral breast away to improve medial access during unilateral interventional procedures. The design of the breast support allows the breast of interest to fall further into the aperture for increased lateral posterior access to the breast during intervention.



#	Component
1	Right Single Loop Coil in Immobilization Frame
2	Biopsy Grid
3	Medial Array Coil
4	Immobilization Frame
5	Left Single Loop Coil in Immobilization Frame

Figure 11: Bilateral Intervention Setup and Components (Without Padding)

The Vanguard Cable

The Vanguard cable connects the Vanguard to the scanner.

CAUTION

A "System Ready" green light appears on the Interface Box when the Vanguard cable is properly plugged in. Do not scan if the cable is unplugged.

The Vanguard cable must be covered with the body pad before operation.

Figure 12: Vanguard Cable Covered with Body Pad

Inserting and Connecting the Coils

To insert a lateral coil, press it into the frame and connect the cable to the interface box. To insert the medial coil, place it in the notch in the middle of the patient support and connect the cable to the interface box. The plugs are keyed to ensure the correct orientation.

Reverse these steps to remove the coils.

NOTE: The connectors on the coils and medial plug are covered with a plastic cap to protect the connector pins from being bent or damaged. You must remove the cover from the connector before you can plug a coil or the medial plug into the interface box. It is recommended that you replace these covers on the connectors when you remove the coils or medial plug to protect them during transportation and storage.

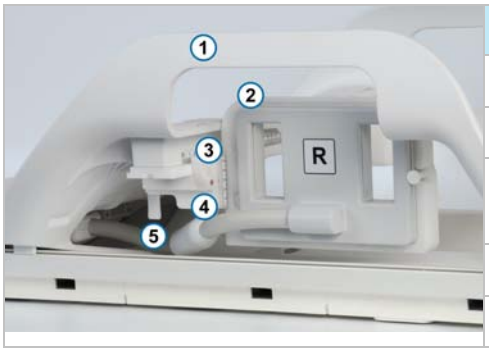
Figure 13: Inserting a Lateral Array Coil

Figure 14: Connecting the Lateral Array Coil

Figure 15: Inserting the Medial Array Coil

Using the Immobilization System

The Vanguard immobilization system holds the breast immobile during scanning. The following figure illustrates the Vanguard immobilization system and components.



#	Component
1	Patient Support Arch
2	Immobilization Frame
3	Lever for Immobilization Frame Release
4	Horizontal Lock
5	Vertical Lock

Figure 16: The Vanguard Immobilization System

Each immobilization frame can be adjusted both vertically and horizontally (anterior/posterior and medial/lateral). Each direction has its own locking mechanism (See the figures below).

To move the immobilization frame up or down, release the vertical lock and move it up or down in its slider. When it is in the desired vertical position, push the lever to lock it in place.

To move the immobilization frame left or right, release the horizontal lock and move the slider left or right along the slider rail. Push the lever to lock the slider when it is in the desired position.

Figure 17: Adjusting Vertical Lock

Figure 18: Adjusting Horizontal Lock

Coil Service

The coils cannot be serviced on site, they must be returned for servicing by a trained representative. Contact your Sentinelle Medical service representative if your coils require servicing (see Contacting Sentinelle Medical on page 12).

Coil Storage

For coil storage, the Sentinelle Medical Companion Cart (part number 4000474-51) is available for purchase. The cart can be used to store coils and coil components. The detachable cabinet can be used as a mobile tray during interventional procedures. Please contact your Sentinelle Medical sales representative for purchasing details.

Figure 19: Sentinelle Medical Companion Cart

Chapter 2

Chapter 2 Quality Assurance (QA)

Instructions for MR Imaging on Phantoms

Sentinelle Medical recommends that the coils be checked for imaging integrity on a regular basis by performing the Quality Assurance (QA) procedure. The QA procedure involves a phantom scan, visually inspecting the QA images, and calculating the signal-to-noise ratio. The phantoms used for the QA scan are part of GE's Unified Phantom Set (GE Model 46-317586G1). The instructions below apply only to the Sentinelle Vanguard system.

NOTE: If small bubbles are apparent on the sides of the phantom, tap the outside of the phantom until these bubbles disappear.

There are two types of QA tests: tests for use with spherical phantoms, and a test for use with rectangular phantoms. Use the appropriate test(s) for the phantoms at your site.

8-Channel Bilateral Breast SNR Verification with Spherical Phantoms

To run the 8-channel bilateral breast SNR verification:

1. Place the Vanguard on the MR scanner table.
2. Install and connect the 8-channel coil set and plug the Vanguard cable into the receptacle.
3. Move the coils to their most lateral position and raise them to their highest vertical position.

4. Place the phantom positioners on either side of the medial coil as shown in the figure below.

Figure 20: Phantom Positioner Setup for 8-Channel Coils

Figure 21: Phantom Setup for 8-Channel Coils

5. Add the spherical GE phantoms and move the coils to their lowest position. Adjust the coils medially so that they lightly touch the phantoms as shown in the figure above.
6. Landmark using the notch on the edge of the patient support as shown below.

Figure 22: Landmark on the Phantoms

7. Do not start a new patient. Instead, open the **Tools** box and start the **Service Browser**.

8. In the **Service Browser**, select the **Image Quality** tab.
9. In the side menu, select **Multi-Coil QA Tool**, then **Click here to start this tool**. The application starts, as shown below.

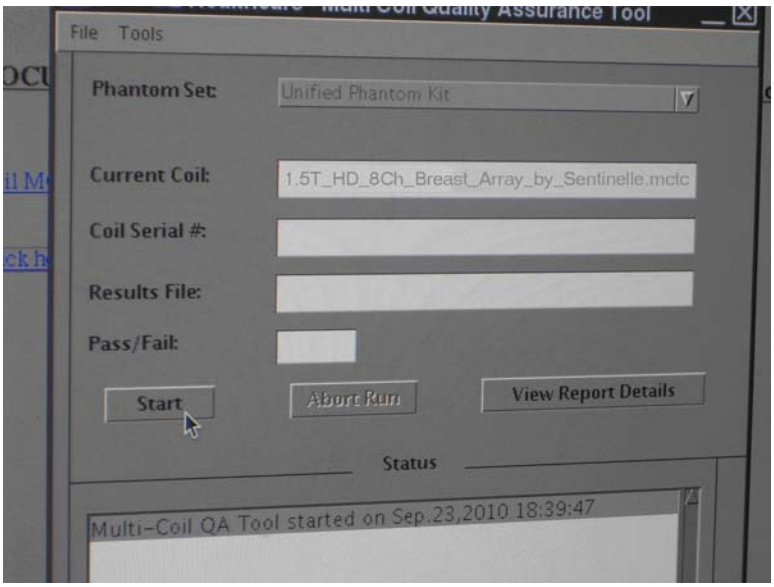


Figure 23: Screen Capture - MCQA Tool Start

10. Click **Start** and answer **Yes** in the dialog that appears.

The MCQA Tool will run for approximately 5 minutes, testing each channel in the system independently. When the tests are complete, the MCQA Tool displays the test results as shown below.

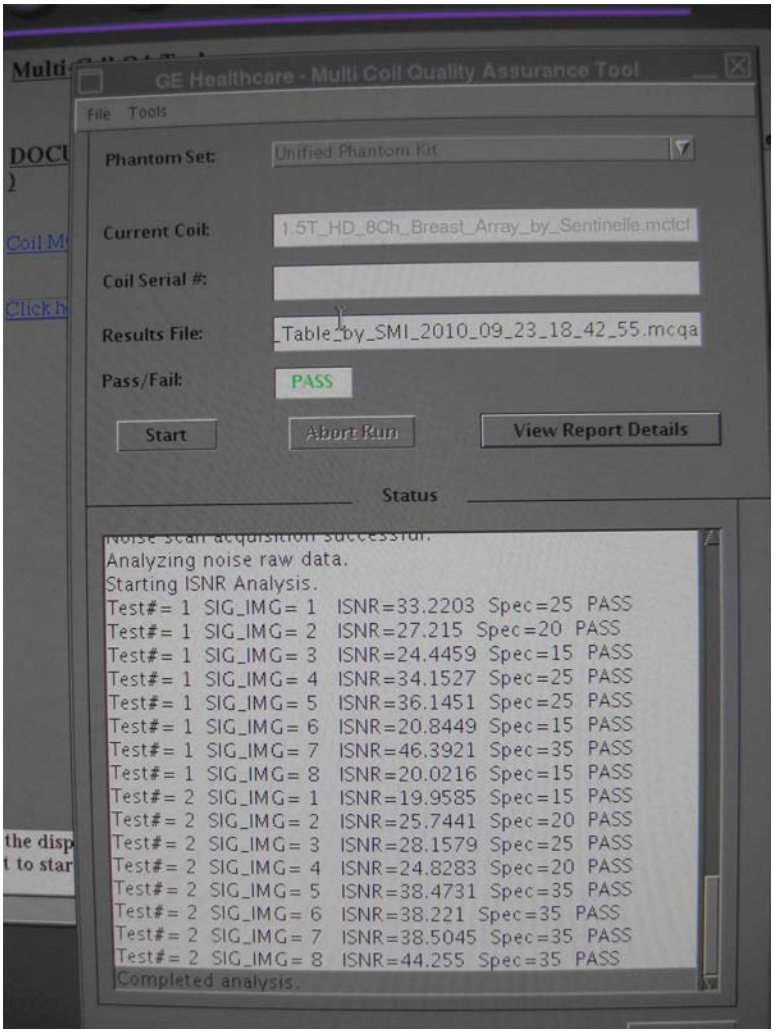


Figure 24: Screen Capture - MCQA Tool Finished

11. If the MCQA indicates that the test failed, check that all coils are connected properly and run the test again. If the test fails a second time, contact your service representative.

4-Channel Bilateral Breast SNR Verification with Spherical Phantoms

To run the 4-channel bilateral breast SNR verification:

1. Place the Vanguard on the MR scanner table.
2. Install and connect the 4-channel coil set and plug the Vanguard cable into the receptacle.

3. Move the coils to their most lateral position and raise them to their highest vertical position.
4. Place the phantom positioners on either side of the medial coil as shown in the figure below.

Figure 25: Phantom Positioner Setup for 4-Channel Coils

Figure 26: Phantom Setup for 4-Channel Coils

5. Add the spherical GE phantoms and move the coils to their lowest position. Adjust the coils medially so that they lightly touch the phantoms as shown in the figure above.
6. Landmark using the notch on the edge of the patient support as shown below.

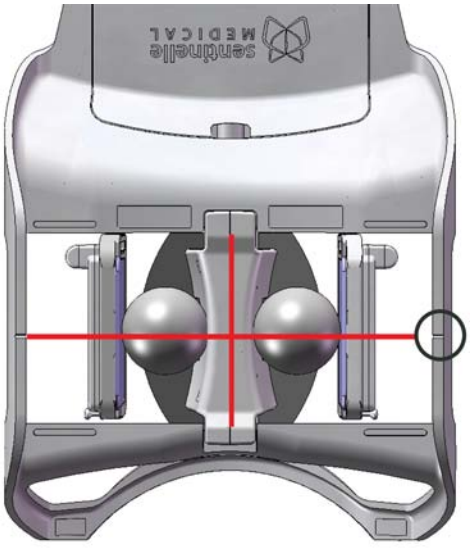


Figure 27: Landmark on the Phantoms

7. Do not start a new patient. Instead, open the **Tools** box and start the **Service Browser**.

8. In the **Service Browser**, select the **Image Quality** tab.
9. In the side menu, select **Multi-Coil QA Tool**, then **Click here to start this tool**. The application starts, as shown below.

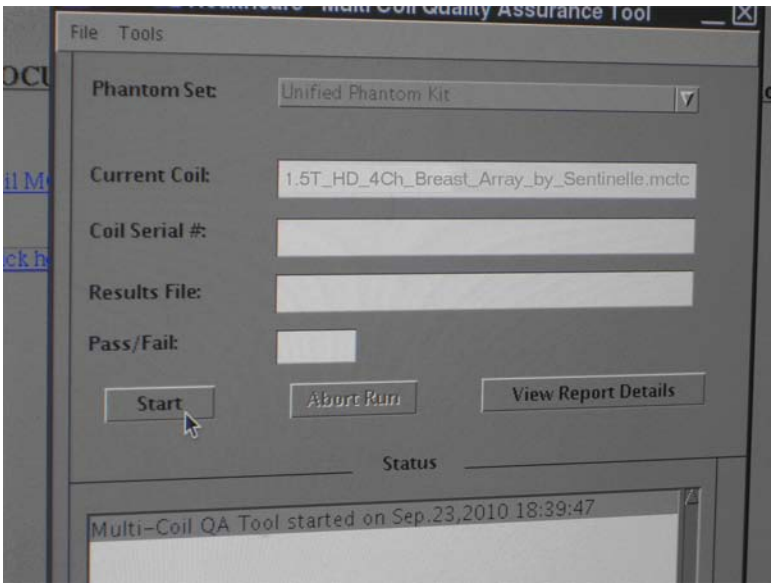


Figure 28: Screen Capture - MCQA Tool Start

10. Click **Start** and answer **Yes** in the dialog that appears.

The MCQA Tool will run for approximately 5 minutes, testing each channel in the system independently. When the tests are complete, the MCQA Tool displays the test results as shown below.

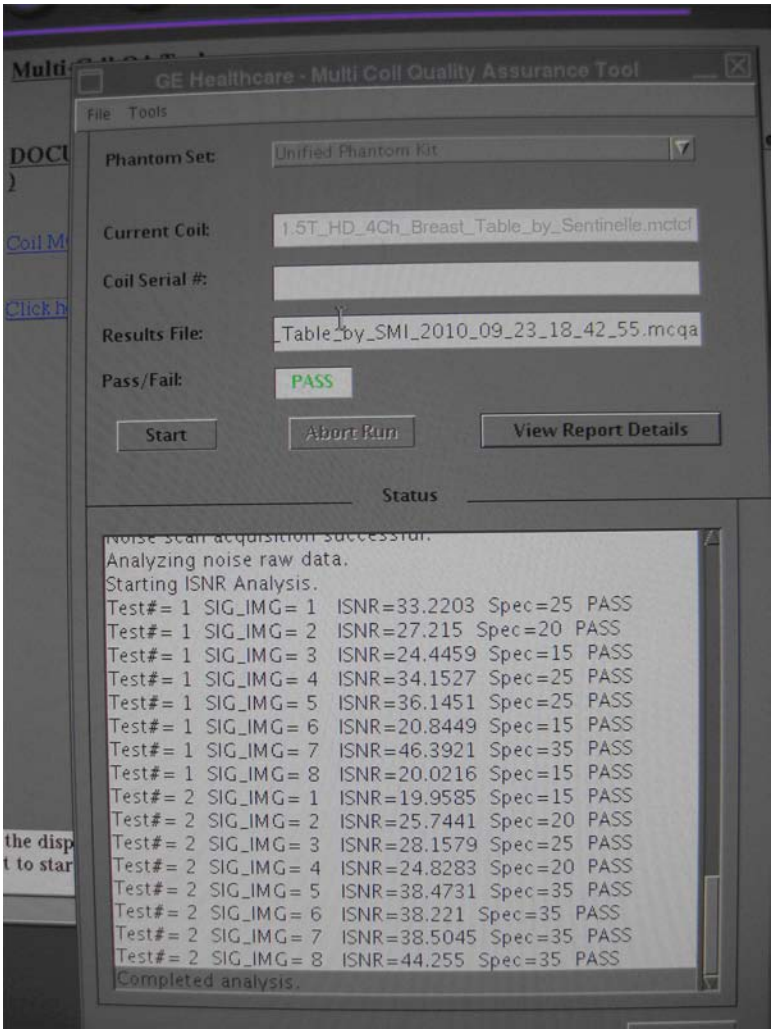


Figure 29: Screen Capture - MCQA Tool Finish

11. If the MCQA indicates that the test failed, check that all coils are connected properly and run the test again. If the test fails a second time, contact your service representative.

Troubleshooting Tips for QA Testing on Spherical Phantoms

Keep the following tips in mind when running the MCQA test:

- Ensure that no patient scan has been started before beginning the MCQA procedure. Exit out of any open patients.
- Landmark the coils before starting the MCQA tool.

- Use only the spherical GE phantoms (GE Model 2360034) and the Sentinelle phantom positioners.
- Verify that the lateral coil A/P position is correct.
- Ensure that all coils are touching the phantoms.
- When the MCQA tool starts, you may see the message shown below. If so, click **Yes** to continue.

Figure 30: MCQA Tool Warning Message

8-Channel Bilateral Breast SNR Verification with Rectangular Phantoms

1. Insert the Vanguard cable into the receptacle.
2. Set up coils for a routine bilateral breast exam using the 8-channel setup. For optimal results, position both lateral coils at the same height. Align the tops of the lateral coils approximately one inch higher than the top of the medial coil.
3. Slide one imaging phantom (part number 5000268-11) between the medial and each lateral coil. Position both phantoms so they are just touching the Medial Array Coil. Lock the horizontal lock. Advance the patient support into the bore.

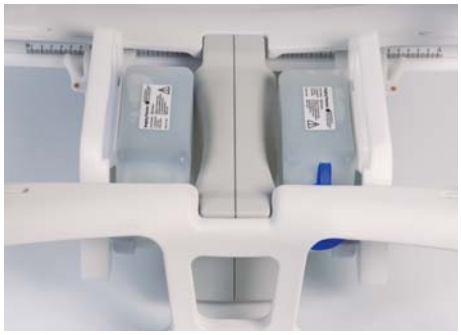


Figure 31: Positioning Phantoms in Holder

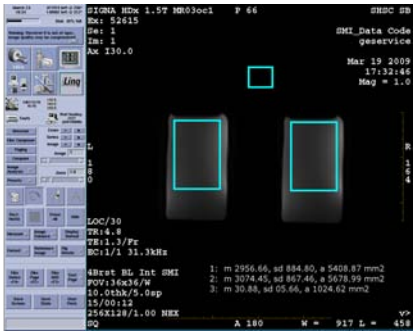


Figure 32: Placing ROIs Over Signal in Phantom

4. At the MR console, prescribe the following scan.

   Patient Information:

   Patient ID: "geservice"

   Patient Name: SMI_ <Date> (for example SMI_26FEB10)

   Patient Weight: "180lbs"

   Coil Configuration:

   Select **currently connected**

   8ch Bilat HD Breast Array by Sentinelle

   8 BrstBL SMI

   Description: 8Ch SNR

   Imaging Parameters:

Scan Plane:	"Coronal"
Field of View:	"32 cm"
Pulse Sequence:	"SE (Spin Echo)"
TR:	"450 ms"
TE:	"14 ms"
Start Location:	"S0.0"
End Location:	"I0.0"
# Slices:	"1"
Slice Thickness:	"5 mm"
Spacing:	"0"
NEX:	"1"
Matrix Size:	"256x256"
BW:	"15.63 kHz"

5. Click **Save Prescription** when done, select the Q/A exam then click the small arrow below scan.
6. Select **Research** > **Download** > **Modify CVs**.
7. Type "saveinter" as the CV name, and "1" as the value. Click **Accept**, then click on the small arrow next to **Scan** > **Research** > **Download**, then scan.
8. Display all images in the series, page through images 1 through 16, and verify that some signal is being received from all channels. Note that channels placed far away from the slice may have low signal.
9. Display the last image in the series using the image viewer found in the browser. Draw three rectangular regions of interest (ROIs) as shown in the figure above.

10. Record the mean value for the left ROI in the **Left Signal Mean** section of the Quality Assurance SNR Table found in the Appendix on page 69. Record the mean value for the right ROI in the **Right Signal Mean** section of the Table.
11. Finally, record the standard deviation for the ROI in the region outside of both phantom signals in the image in the **Noise Standard Deviation** section of the Quality Assurance SNR Table.
12. Calculate the Signal-to-Noise Ratio (SNR) and record it in the Quality Assurance SNR Table. SNR is computed using the following equation:

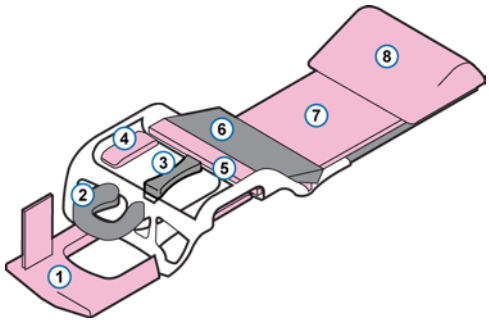
$$\textbf{SNR} = \frac{\textbf{(Left Signal Mean + Right Signal Mean) / 2}}{\textbf{Noise Standard Deviation}}$$

NOTE: All values should be entered into the Quality Assurance SNR Table provided in the Appendix section of this manual and compared with baseline SNR measurements (values from tests performed during installation). Acceptable SNR values should have a variance of ±25% of the baseline values. Larger or smaller value may be indicative of problems with the coils or imaging system. If these values are not within an acceptable range, please contact Sentinelle Medical. For contact information, see Contacting Sentinelle Medical on page 12.

Chapter 3

Chapter 3 Patient Positioning and Preparation Guidelines

This chapter describes how to position the Vanguard pads for optimum comfort. See the following figure for the recommended pad placement. In all cases, use the body pad and the body wedge pad. Ensure that the body wedge pad covers the edge of the patient support below the ribs.



#	Component
1	Front Pad
2	Headrest Pad
3	Medial Array Pad
4	Shoulder Support Pads
5	Body Wedge Pad
6	Hip Wedge Pad
7	Body Pad
8	Foot Rest Pad

Figure 33: Padding Setup

Figure 34: Patient Lying Prone on the Vanguard

Weight Support

Refer to the Specifications table on page 18 of this manual for maximum patient weight specifications.

To correctly support the patient's weight, the patient support must be properly seated on the MRI table stretcher.

CAUTION

Advise the patient not to place their hands on the coil elements when mounting and dismounting the system. Putting weight on the coils may damage them.

Breast Positioning Guidelines

The figure below depicts guidelines for proper breast positioning. The general rule implies that the inferior border of the breast aligns just within the border of the medial coil. The inferior border of the breast should never be positioned further inferior than the border of the medial coil.

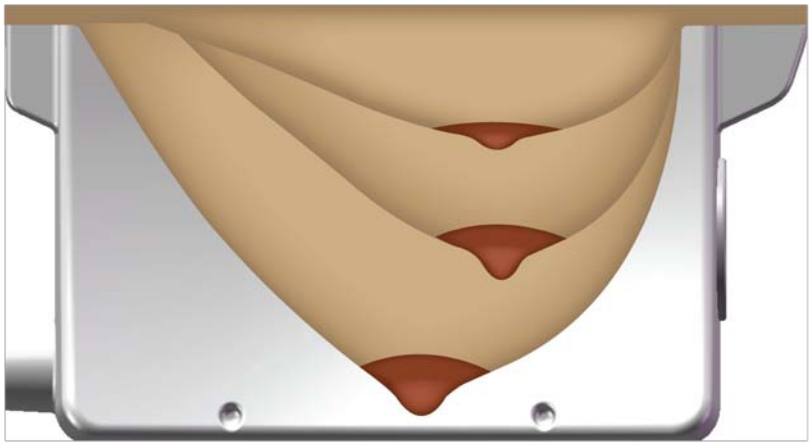
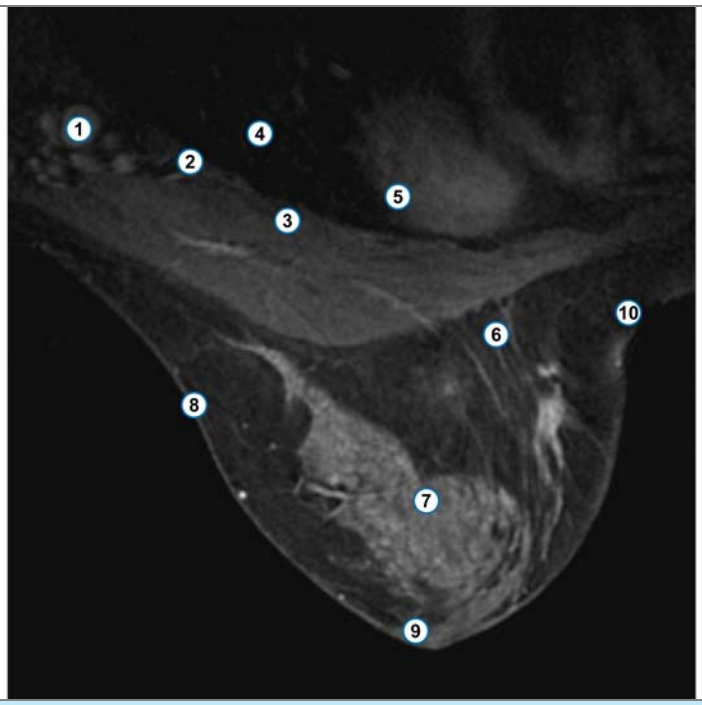


Figure 35: Breast Positioning Guidelines for Small, Medium and Large Breasts

NOTE: It may be helpful to remove the Immobilization Frame to get a clearer view of how the breast is positioned. Replace the Immobilization Frame when the breast is positioned correctly.

The figure below depicts the anatomy of the breast. Position the patient such that the scan will include the anatomy of interest.



#	Anatomical Feature
1	Axillary Lymph Nodes
2	Pectoralis Minor Muscle
3	Pectoralis Major Muscle
4	Lung
5	Heart
6	Cooper’s Ligaments
7	Parenchyma
8	Skin
9	Nipple
10	Inframammary fold

Figure 36: Breast Anatomy

Arm Positioning

Sentinelle Medical recommends arms-back positioning. If the patient’s arms will not fit between the arches of the patient support, use the arms-forward positioning. Shoulder supports and shoulder support pads provide additional patient comfort by reducing sternum and rib pressure when using the arms-back position, but are not recommended for arms-forward positioning.

If the patient is in the arms-forward position, the hand separation pad must be used between patient's hands so that a loop is not created.

Figure 37: Arms-Back Position

Figure 38: Arms-Forward Position

Figure 39: Incorrect Hand Positioning

Figure 40: Correct Hand Positioning

The following table describes how to position the shoulder supports and pads.

Table 9: Shoulder Support Placement

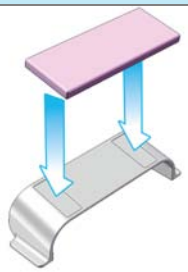
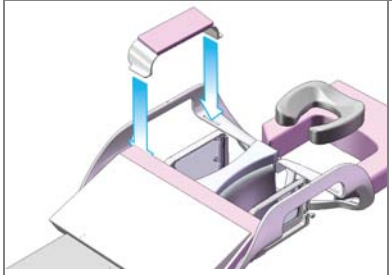
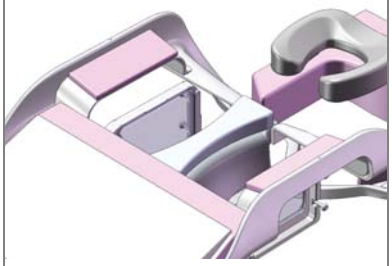
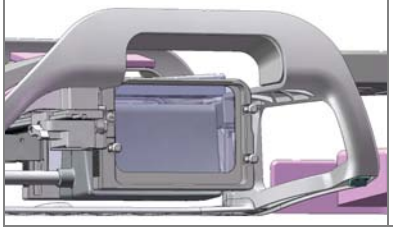
Image	Instruction
	**Step 1.** Attach shoulder support pad to shoulder support. Position immobilization frame approximately 50mm (two inches) from arch.
	**Step 2.** Place shoulder support with attached shoulder support pad between the immobilization frame and the arch. Make sure the tabs on the shoulder support "feet" are positioned in the grooves on the patient support. The immobilization frame should fit under the medial side of the support.

Image	Instruction
	**Step 3.** Repeat steps 1 and 2 for the opposite shoulder support. The supports should be placed as far laterally as possible before the patient is placed on the tabletop. The body wedge pad should be pulled up to meet the shoulder support pads ensuring there is no gap between the body wedge pad and the edge of the patient support.
	*NOTE: Make sure the shoulder support stays in place during the procedure. This will help relieve pressure on the patient's sternum.*

Arms-Back Positioning

When positioning patients with their arms back:

- Ensure their arms are by their sides.
- Remove the front pad for better air flow. The front pad is optional for arms-back positioning.
- Use shoulder support bridges and pads to support torso weight and release pressure from the sternum. The shoulder support bridges and pads can be added after positioning the coils.
- Use the hip wedge pad. Raising the hips flattens the back and relieves pressure on the sternum. Placing the hip wedge pad under the body wedge pad may increase comfort for some patients.
- Adjust the headrest height – the head should be aligned with spine to help release pressure from the sternum.
- Use foot rest pad. Position the foot rest pad with the edge aligned with the patient’s knees, supporting the feet.

Arms-Forward Positioning

When positioning patients with their arms forward:

- If the patient is in the arms-forward position, the hand separation pad must be used between patient’s hands so that a loop is not created.

- Use the front pad to comfort the arms. Note that the patient's arms might become numb with arms-forward positioning.
- Remove the shoulder support pads.
- Use the hip wedge pad. Raising the hips flattens the back and relieves pressure on the sternum. Placing the hip wedge pad under the body wedge pad may increase comfort for some patients.
- Use foot rest pad. Position the foot rest pad with the edge aligned with the patient's knees, supporting the feet.

IV Management

Intravenous protocols differ from site to site. Follow the protocol established at your facility.

- For unilateral interventional procedures, the IV is ideally inserted into the arm opposite to the side of the biopsy. This arm can be positioned over the patient's head for easy access during the procedure.
- Have the injection pump ready before the patient enters the exam room.
- While patient is being positioned on the Vanguard, attach the extension tubing to IV.
- With the patient lying with their arms back, loop the extension tubing over patient's thumb. Extend the tubing over the patient's back and secure the position with tape i.e. you can place a piece of tape over the patient's shoulder.
- Flush IV with saline to ensure proper position. Feel the flush go through the arm. Ask the patient if there is any pain.
- As the patient is shuttled into scanner, ensure the extension tubing and other pieces of equipment lie within the patient support and never outside the patient support arches.

CAUTION

To avoid possible patient injury, do not use the automatic button to advance the patient into the scanner. Use the manual advance button and watch for potential contact of the patient with the bore as they advance into the scanner.

- Position the injector close to the MR scanner.

Chapter 4

Chapter 4 Imaging with the Vanguard

This chapter outlines how to set up and use the Vanguard for bilateral breast imaging. Use the same procedure, adjusted appropriately, for unilateral breast imaging.

Safety Precautions

Do not handle the electrical pins in the connector housings of the system plug, the coil connectors in the cable tray, or the coils. Electrostatic discharge could damage the equipment.

CAUTION

To avoid possible patient injury, do not use the automatic button to advance the patient into the scanner. Use the manual advance button and watch for potential contact of the patient with the bore as they advance into the scanner.

Keep limbs away from the gap between the Vanguard and the scanner while raising and lowering the MR patient table.

Patients must not form a loop with any body parts while scanning. For example, they cannot touch any part of the right hand or arm to any part of the left hand or arm. This could cause a burn at the point of contact. Use pads to prevent any part of the patient's body from touching metal on the patient table. Educate the patient accordingly and check the patient's position immediately before the scan.

Imaging Procedure

Checklist

- 2 Lateral Array Coils, or 2 Single Loop Coils for 4-channel imaging if that configuration is available with your system
- 1 Medial Array Coil
- 2 Clear Immobilization Plates
- Padding

System Setup and Patient Positioning

1. Adjust the Vanguard padding to accommodate for patient size and comfort. Larger patients may require less padding. See the Patient Positioning and Preparation Guidelines Chapter, beginning on page 43 for details.
2. Wipe down all padding with an approved disinfectant (see Cleaning on page 62) and lay clean linens on all surfaces that may contact the patient.
3. Open the immobilization frames to their most lateral position.
4. Attach the appropriate coils and insert clear immobilization plates. See Inserting and Connecting the Coils on page 29 for more information.

Figure 41: Inserting an Immobilization Plate

5. Open the cover of the interface box under the ramp pad and connect the lateral array coils (left and right) and medial array coil to the connection ports.
6. Ensure the Vanguard cable is plugged into the correct scanner port and the green light is on.
7. Ensure the patient is wearing appropriate hearing protection.
8. Lower the scanner table.
9. Assist the patient onto the Vanguard. Patients can steady themselves with the patient support arches as they lower their breasts into the aperture.
10. Position the patient's arms as per the guidelines in the Patient Positioning and Preparation Guidelines Chapter, beginning on page 43.
11. Ensure the patient is aligned centrally on the patient support.

12. The patient may have to adjust their position so that their breasts are centered with respect to the immobilization plates.
13. Pull the breast tissue down and away from the chest wall ensuring no tissue is caught on the posterior side of the immobilization plate or sternum support.
14. Smooth breast tissue on the lateral side with thumb to remove mammary fold.
15. With the coil set at optimal height, release the horizontal lock on the slider and move it medially to offer immobilization but not compression of the breast. Lock the slider. Repeat positioning for the contralateral breast.

    NOTE: This figure shows the immobilization frames set at optimal height, with the gap between the lower edge of the rectangular feature and the bottom round feature aligned at the 2 cm mark on the vertical scale.

Figure 42: Immobilization Frame Set at Optimal Height

16. Adjust the headrest as needed.
17. Relieve pressure on the patient's sternum by positioning the hip wedge pad to raise the hips and flatten the back. If a hip wedge pad is not available, a pillow in the same position will suffice.
18. Place the foot rest pad under the patient's legs to improve comfort.
19. Advance the patient into the MR scanner, landmark on the centre of the coils and advance patient support to scan.
20. Proceed with the imaging protocol.

Post-Examination Procedures

1. Shuttle the patient out of the MR scanner.
2. Release the immobilization frames.
3. Assist the patient off the Vanguard.
4. Clean all Vanguard surfaces following the instructions in the Maintenance Chapter, beginning on page 61.

Chapter 5

Chapter 5 Interventional Procedures with the Vanguard

This chapter describes how to set up and use the Vanguard for unilateral and bilateral interventional procedures.

NOTE: This chapter is not applicable to an 8-channel imaging-only system.

Always review the patient's previous imaging to find where the target is before the exam. This allows you to set up the Vanguard properly and optimize patient positioning.

Safety Precautions

Do not handle the electrical pins in the connector housings of the system plug, the coil connectors in the cable tray, or the coils. Electrostatic discharge could damage the equipment.

CAUTION

To avoid possible patient injury, do not use the automatic button to advance the patient into the scanner. Use the manual advance button and watch for potential contact of the patient with the bore as they advance into the scanner.

Keep limbs away from the gap between the Vanguard and the scanner while raising and lowering the MR patient table.

Patients must not form a loop with any body parts while scanning. For example, they cannot touch any part of the right hand or arm to any part of the left hand or arm. This could cause a burn at the point of contact. Use pads to prevent any part of the patient's body from touching metal on the patient table. Educate the patient accordingly and check the patient's position immediately before the scan.

Safety Notices for Interventional Procedures

The following safety notices apply specifically to interventional procedures with the Vanguard.

WARNING

Performing interventional procedures on female patients with breast implants may cause the implant to rupture.

If a biopsy has previously been performed, do not use MR reference images created before the biopsy. Create new MR images in case the anatomy changed as a result of the biopsy.

Perform a biopsy only when both the marker and lesion are located within an ellipsoid with the following axial expansions about the magnet iso-centre: x (right/left) = 44 cm, y (anterior/posterior) = 26 cm, z (head/feet) = 26 cm. Objects outside this area may not be accurately represented in images due to due to the presence of significant field inhomogeneities, which could result in the biopsy missing the lesion.

To select the reference position, select only slices that run parallel to the grid (sagittal slices). Measure the slices without slice distance and a slice thickness less than or equal to 2 mm.

Select the tip of the marker to compute the reference position.

CAUTION

Use a needle block that corresponds to the diameter of the needle thickness.

Use biopsy needles whose lengths correspond to the calculated puncture depth.

To correctly position the needle, take the length of the needle block into account. Consult the documentation provided by the needle vendor regarding selecting the correct needle depth.

Equipment Checklist

Unilateral Intervention

- 1 Contralateral Breast Support
- 1 Right Single Loop Coil
- 1 Left Single Loop Coil
- Medial Plug
- 2 Biopsy Grids
- MRI Biopsy Worksheet (Provided by Sentinelle Medical or your needle vendor)

NOTE: Biopsy grids are not included with the GE catalog offering. These products can only be ordered directly from Sentinelle Medical.

Bilateral Intervention

- 1 Right Single Loop Coil
- 1 Left Single Loop Coil
- 1 Medial Array Coil
- 2 Biopsy Grids
- MRI Biopsy Worksheet (Provided by Sentinelle Medical or your needle vendor)

NOTE: Biopsy grids are not included with the GE catalog offering. These products can only be ordered directly from Sentinelle Medical.

Biopsy Supplies Not Included (Recommended)

The following list is an example of supplies that may be required when performing biopsies. These supplies are not provided by Sentinelle Medical. Discuss with the respective needle vendor specific supplies that are required for the vacuum assisted device prior to the biopsy date.

Sterile Tray

- Sterile drape on which to place sterile supplies
- Sterile gloves
- Povidone-iodine topical antiseptic swabs
- Local anaesthetic
- Local anaesthetic with Epinephrine
- 3cc Syringe (1)
- 10cc Syringe (2)
- 18G 1½" needle (to draw anaesthetic)
- 25G 1½" needle (for anaesthetic prior to skin nick)
- 22G 3" needle (for anaesthetic administration w/deeper lesion)
- Scalpel (#11)
- 4x4" gauze
- 2x2" gauze
- Thumb forceps

Disposables Non-Sterile

- Chucks, towels, or absorbent non-sterile material
- Auto or Manual Fiducial markers (2 Auto Fiducials or up to 6 Manual Fiducials for bilateral interventional procedures, or 1 Auto Fiducial or up to 3 Manual Fiducials for unilateral interventional procedures), or vitamin E capsules
- Non-sterile gloves

Post Procedure Prep Checklist

- Large Formalin Container (for specimen)
- Pathology information/request form
- Gauze for post biopsy-compression
- Steri-strips™ to close incision
- Medical dressing to cover steri-strips™ (optional)
- Cold pack
- Post-procedure information sheet
- Large sharps container

Other Required Equipment Not Supplied by Sentinelle Medical

- Absorbent Pads
- Post Operative Care Sheet
- Biohazard Waste Containers

Interventional Procedure

Frames and Coils Setup for Bilateral Procedures

Follow these steps to set up the Vanguard for bilateral interventional procedures. See the next section for setup instructions for unilateral procedures.

1. Unplug and remove the lateral array coils.
2. Position the immobilization frames to their most lateral position.
3. Remove the clear immobilization plates from the immobilization frames and replace them with sterile biopsy grids.

Figure 43: Removing Clear Immobilization Plates

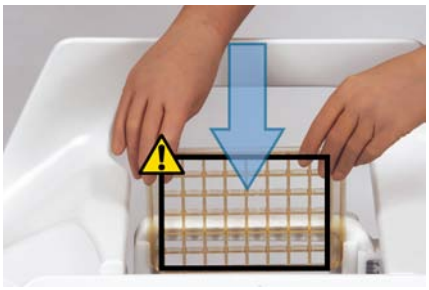


Figure 44: Inserting Biopsy Grid

CAUTION

Always follow your clinical gloving procedures to ensure that the sterility of the grid surfaces is not compromised.

NOTE: The sterile biopsy grid is a single-use device. Reusing this device risks patient infection and/or the spread of pathogens.

NOTE: Biopsy grids are not included with the GE catalog offering. These products can only be ordered directly from Sentinelle Medical.

4. Install the single loop coils in the uppermost position in the immobilization frames, and connect them. If the top or bottom row of the grid is blocked by the single loop coil, move the single loop coil anteriorly/posteriorly in the immobilization frame to allow access.
5. If the medial coil is not already in place, insert it and connect it.

Frames and Coils Setup for Unilateral Procedures

Follow these steps to set up the Vanguard for unilateral interventional procedures. See the previous section for setup instructions for bilateral procedures.

1. Remove the medial and lateral array coils.
2. Remove the clear immobilization plates from the immobilization frames and replace them with sterile biopsy grids.

Figure 45: Removing Clear Immobilization Plates

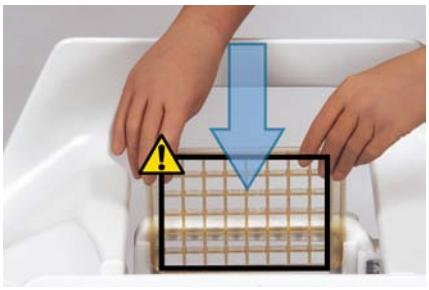


Figure 46: Inserting Biopsy Grid

CAUTION

Always follow your clinical gloving procedures to ensure that the sterility of the grid surfaces is not compromised.

NOTE: The sterile biopsy grid is a single-use device. Reusing this device risks patient infection and/or the spread of pathogens.

NOTE: Biopsy grids are not included with the GE catalog offering. These products can only be ordered directly from Sentinelle Medical.

3. Unlock the horizontal locks of the immobilization frames and slide both frames to the side of intervention (right for right breast and left for left breast).
4. Place the contralateral breast support to support the opposite breast during the procedure. Ensure the support is angled down lateral to medial.
5. Position the medial immobilization frame beside and at the same height as the contralateral breast support. Lower slightly and lock in place.
6. Position the lateral immobilization frame to its most lateral position.
7. Install the single loop coils in the uppermost position in the immobilization frames, and connect them. If the top or bottom row of the grid is blocked by the single loop coil, move the single loop coil anteriorly/posteriorly in the immobilization frame to allow access.
8. Plug the medial plug into the medial connector.

Patient Positioning

1. Adjust the Vanguard padding to accommodate for patient size and comfort. Larger patients may require less padding. See the Patient Positioning and Preparation Guidelines Chapter, beginning on page 43 for details.
2. Wipe down all padding with an approved disinfectant (see Cleaning on page 62) and lay clean linens on all surfaces that may contact the patient. and lay clean linens and absorbent pads on the table surface and all surfaces that may contact the patient, including the Contralateral Breast Support if present.

3. Clean and prepare the patient's breast according to site policies and procedures.
4. Ensure the patient is wearing appropriate hearing protection.
5. Lower the scanner table.
6. Assist the patient onto the Vanguard. Patients can steady themselves with the patient support arches as they lower their breasts into the aperture.

   For unilateral procedures, the target breast will be between the two biopsy grids and the opposite breast will rest comfortably on the contralateral breast support.

   For bilateral procedures, each breast will be between a biopsy grid and the medial array coil.
7. Raise the scanner table for easier patient positioning.
8. Position the patient's arms as per the guidelines in the Patient Positioning and Preparation Guidelines Chapter, beginning on page 43.
9. Ensure the patient is aligned centrally on the patient support.
10. Have the patient adjust their position as necessary to ensure that the region of interest is centered with respect to the biopsy grid.
11. Adjust the headrest as needed.
12. Relieve pressure on the patient's sternum by positioning the hip wedge pad to raise the hips and flatten the back. If a hip wedge pad is not available, a pillow in the same position will suffice.
13. Pull the breast tissue down and away from the chest wall, ensuring no tissue is caught on the sternum support.
14. (Unilateral procedures only) Apply light immobilization by moving the medial frame. Once positioned, ensure the medial frame is locked both horizontally and vertically.
15. Smooth breast tissue on the lateral side with thumb to remove mammary fold.
16. Apply sufficient immobilization with the lateral grid to keep the breast in position. The breast should feel like the palm of your hand when fingers are extended.
17. If you are using a Sentinelle Auto Fiducial, place it in grid window C4. Otherwise, place your fiducials or vitamin E capsules in grid windows in close proximity to the target. Document these locations on the appropriate grid worksheet (provided by Sentinelle Medical or your needle vendor).

    NOTE: Sentinelle Auto Fiducials are for use with Sentinelle Medical Aegis software only. If you are not using Aegis to analyze your MR images, you must use manual fiducials or vitamin E capsules.

18. For bilateral procedures, repeat this process (positioning the breast, applying immobilization with the biopsy grid, and placing fiducials in the appropriate grid window) for the other breast.

Figure 47: Pulling Breast Tissue Down (Grid Removed to Show Detail)

Figure 48: Automatic Fiducial Marker in Grid

19. Place the foot rest pad under the patient's legs to improve comfort.
20. Ensure the Vanguard cable is plugged into the correct scanner port and the green light is on.
21. Advance the patient into the MR scanner, landmark on the centre of the coils and advance patient support to scan.
22. Proceed with the imaging protocol.

Post-Examination Procedures

1. Shuttle the patient out of the MR scanner.
2. Release the immobilization frames.
3. Treat the biopsy site according to your site's recommendations.
4. Assist the patient off the Vanguard.
5. Dispose of the grids in a biohazard container.
6. Clean all Vanguard surfaces following the instructions in the Maintenance Chapter, beginning on page 61.

Chapter 6

Chapter 6 Maintenance

Storage and Operating Conditions

Coils and apparatus should be stored at the same room temperature and relative humidity as the MR scanner. Storing the Vanguard in the MR Suite and scanner room is acceptable.

When not in the scanner room, transport and store the Vanguard and all components, except the phantoms, under the conditions described in the following table. Do not store the phantoms at temperatures below 0º Celsius.

Table 10: Transportation and Storage Environment

	Minimum	Maximum
Ambient Temperature (°C)	-30	+65
Relative Humidity (non-condensing)	10%	95%
Atmospheric Pressure	500 hPa	1060 hPa

Table 11: Operating Conditions

	Minimum	Maximum
Ambient Temperature (°C)	+16	+25
Relative Humidity (non-condensing)	40%	60%

Inspection

Inspect the coils weekly for signs of mechanical damage or breakage. Inspect to see that the system fits securely in the MR scanner patient table and that the patient table motion into the scanner is smooth and regular.

CAUTION

Do not use the Vanguard if it has sustained mechanical damage or if patient support motion is significantly compromised. Contact a Sentinelle Medical representative immediately for the best course of action.

It is important to inspect the coils to ensure the coil enclosure is not cracked or otherwise compromised in such a way that it may no longer be watertight. If you

suspect a coil may be damaged, contact a Sentinelle Medical service representative. For contact information, see Contacting Sentinelle Medical on page 12.

Special Care Requirements

Cleaning

The Sentinelle Medical biopsy grids are sterile, single-use disposable items. The following parts, however, should be cleaned before and after each use.

NOTE: Use protective gloves to perform these cleaning tasks, and always comply with your site's biohazard/blood-borne pathogen safety protocols.

Routine Imaging:

- The Vanguard Immobilization System
- Padding
- Medial Array Coil
- Left and Right Lateral Array Coils

Interventional Imaging:

- The Vanguard Immobilization System
- Padding
- Fiducials
- Left and Right Single Loop Coils
- Medial Array Coil (for Bilateral Interventions)
- Contralateral Breast Support (for Unilateral Interventions)
- Catchment Tray

The cleaning solutions listed in the table below have been tested and are recommended for cleaning the apparatus and the coils. Use a cotton cloth to clean the coils, system surfaces, and padding.

CAUTION

The coils are not waterproof and should not be immersed in any liquid. This will damage the coils and may cause injury.

Do not use cleaning solutions not listed in this table as they may damage the system. Sentinelle Medical must approve any proposed cleaning solutions.

NOTE: To avoid soiling the coils, place a cotton sheet over the coil surfaces before positioning the patient. If a coil becomes soiled, clean it as described.

Table 12: Approved Cleaning Solutions

Solution	Comments
Warm water	Safe for all areas.
Commercial dish washing liquid/water combination	Safe for all areas.
Alcohol solution (70%, isopropyl alcohol, 30% water).	Safe for patient support surfaces, coil housings, and immobilization plates. Do not apply to Padding surfaces. Do not apply to adhesive-backed materials such as labels and Velcro® fasteners.
Hydrogen Peroxide-based cleaners (e.g., Virox, G-Force® H2O2 and Accel TB™)	Safe for patient support surfaces, coil housings, and immobilization plates. Do not apply to Padding surfaces. Do not apply to adhesive-backed materials such as labels and Velcro® fasteners.
Anticeptizyme	Safe for use on immobilization frames, patient support, and coil housings to break up bodily fluids as needed.
Virex TB	Safe for Padding.
Heptagon II Disinfectant Spray	Safe for Padding.
VC 79	Safe for Padding.

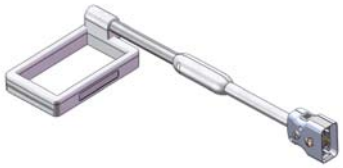
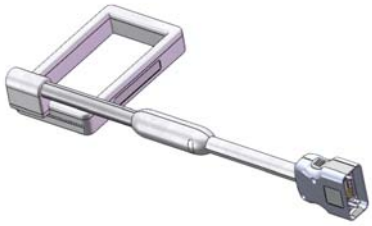
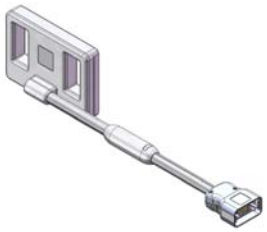
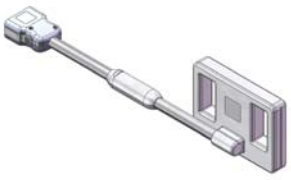
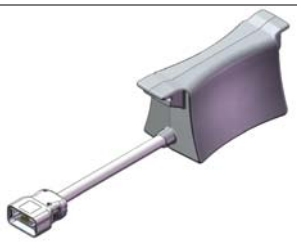
NOTES:

- Do not apply tape to the top surface of the padding.
- Do not mark the padding with ink.
- Do not immerse the coil cable in cleaning fluid. Isopropyl alcohol can be used to wipe the contacts as required.
- If bodily fluids contact immobilization frames or coil enclosures, use the appropriate decontamination techniques to clean them.
- Clean all waste from the coil using 1:10 bleach/water solution and a cloth.
- Ensure coil enclosure is intact and is not permeable to fluid.
- Coils cannot be sterilized using any autoclaving techniques.

Replaceable Components/Accessories

The following tables list the system accessories that may be purchased for replacement:

Table 13: Replaceable RF Components

Part	Part Name	Sentinelle Medical Part Number
	Left Single Loop Coil	4000205-11
	Right Single Loop Coil	4000204-11
	Left Lateral Array Coil	4000203-11
	Right Lateral Array Coil	4000202-11
	Medial Array Coil	4000209-11

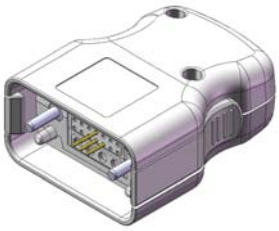
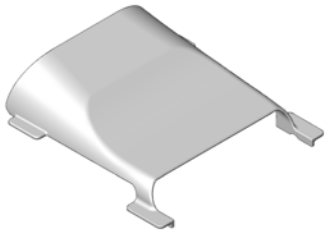
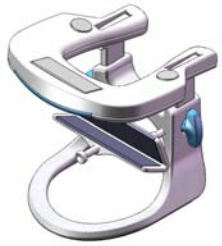
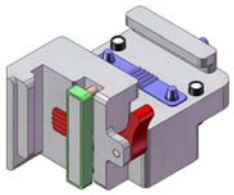
Part	Part Name	Sentinelle Medical Part Number
	Interface Box	PRD-01504
	Medial Plug	PRD-01509

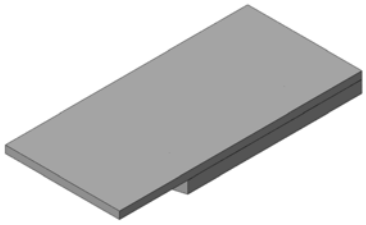
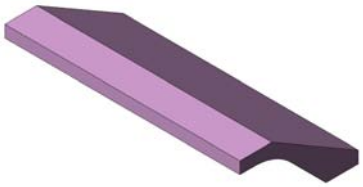
Table 14: Replaceable Hardware Accessories

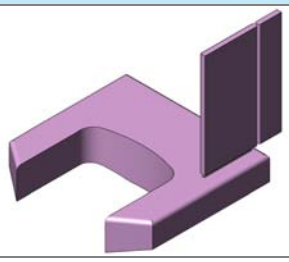
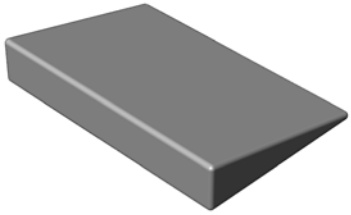
Part	Part Name	Sentinelle Medical Part Number
	Contralateral Breast Support	SVC-00386
	Catchment Tray	SVC-00331
	Headrest	SVC-00318

Part	Part Name	Sentinelle Medical Part Number
	Left Immobilization Frame	SVC-00386
	Right Immobilization Frame	SVC-00385
	Horizontal Slider Assembly LEFT	SVC-00383
	Horizontal Slider Assembly RIGHT	SVC-00384

The following table lists the padding accessories that may be purchased for replacement:

Table 15: Padding Accessories

Part	Part Name	Sentinelle Medical Part Number
	Body Pad	SVC-00328
	Body Wedge Pad	SVC-00326
	Headrest Pad	SVC-00308
	Shoulder Support Pad	SVC-00327
	Foot Rest Pad	SVC-00320

Part	Part Name	Sentinelle Medical Part Number
	Front Pad	SVC-00325
	Medial Array Pad	SVC-00322
	Hip Wedge Pad	SVC-00309

Appendix A

The following chart can be copied and used when calibrating and checking the SNR on the Vanguard, as described in the Quality Assurance Chapter, beginning on page 33.

Table 16: Baseline SNR Measurements

Date	Left Signal Mean	Right Signal Mean	Noise Standard Deviation	SNR

Table 17: Quality Assurance Record

Date	Left Signal Mean	Right Signal Mean	Noise Standard Deviation	SNR

HOLOGIC™
The Women's Health Company

Sentinelle - A Division of Hologic
Breast MRI Disposables Order Form

FROM:
Hologic, Inc.
6100 Technology Center Drive
Indianapolis, IN 46278 USA
Phone: 317.344.7590
Fax: 317.344.7690
Toll Free: 877.877.8767
Email: csfax@hologic.com

SHIP TO: _____
Address: _____
_____

BILL TO: _____
Address: _____
_____

Account Number	
Purchase Order Number	
Account Contact	
Account Telephone	
Account Fax	

*** Payment Terms: Net 30 days, freight pre-paid and added to invoice. All shipments are FOB origin.**

Part Number/Description	Box Qty	Price Per Box	Number of Boxes (to be ordered)
5000137-51 (Sterile Biopsy Grids for use with Vanguard) Biopsy Grids are for use with the Vanguard Breast MRI Table or Tabletops. Supplied individually in sterilized boxes of ten, the 48 apertures permit unrestricted access to the breast.	10	$400.00	
SM-0511 (Disposable Table Covers) Breathable, environmentally-friendly, soft and tailored custom-fit disposable table covers.	25	$150.00	
SM-0517 (Disposable Headrest Covers) Breathable, environmentally-friendly, soft and tailored custom-fit elastic headrest covers.	25	$150.00	
5000434-11 (Automatic Fiducial Kit) Kit includes two Automatic Fiducial Markers and one box of Amiga Disposable Fiducial MRI Spot Markers.	1 ea	$150.00	
5000435-11 (Automatic Fiducial Marker) Automatic Fiducial Marker is used in combination with the MRI Spot Markers to provide the highest level of confidence and accuracy when using Aegis Breast Software for locating targets within tissue.	1 ea	$50.00	
4000345-11 (Manual Fiducial Kit) Kit includes six Manual Fiducial Markers and one box of Amiga Disposable Fiducial MRI Spot Markers.	1 ea	$150.00	
5000287-11 (Manual Fiducial Marker) Automatic Fiducial Marker is used in combination with the MRI Spot Markers to provide the highest level of confidence and accuracy when using Aegis Breast Software for locating targets within tissue.	1 ea	$50.00	
721 (Amiga Disposable Fiducial Spot Markers) Amiga Disposable Fiducial MRI Spot Markers are easy to use and highly visible under MRI.	10	$120.00	
6V-HDM (Batteries for lighting system on Vanguard Table for GE) Replacement batteries for the Sentinelle Breast MRI Table for GE lighting system come in a package of two batteries.	2	$60.00	

Anticipated Delivery Date: _____

CUSTOMER SIGNATURE: _____ **Date:**_____