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Customer Technical Bulletin

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Author: Service Engineering and Research & Development

Product: Selenia / Selenia Dimensions/ 3Dimensions / Affirm Prone Biopsy

Subsystem: Detector

Subject: EMI Recommendations for Installations

Document Version Note

Revision 5 of this document includes the following changes:

- Additional information about the ELF meter and Detector EMI spectrums
- General EMI screening process.

EMI Recommendations for Installations

EMI, Electromagnetic Interference, is a naturally occurring or manmade phenomenon that can detrimentally impact image quality. It is often broadly defined as a kind of radiation including visible light, radio waves, gamma rays, and X-rays, in which electric and magnetic fields vary simultaneously. Figure 1 below illustrates conceptually the two components of electromagnetic radiation, namely the electric wave orthogonal to the magnetic wave.

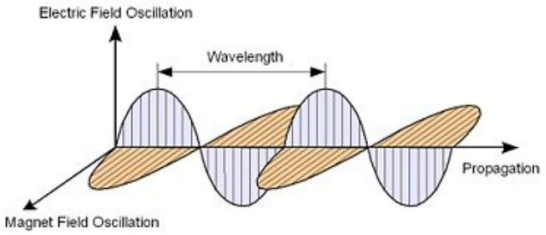

Figure 1: Definition of electromagnetic wave.

As such, the magnetic field strength (B-field), the electric field strength (E-field) and the frequency (Wavelength) are all required to adequately define a specific electromagnetic wave. As mentioned above, the frequency can be unique (in the case of a sine wave) or can encompass a range of frequencies, called a spectrum. It is this spectrum that must be fully understood to determine the susceptibility of a given device to EMI. This is based on the full characteristics of the nature of radiation (magnetic field strength, electric field strength and frequency) in comparison to the sensitivity of the target device.

The construction of the detector used in Selenia Dimensions includes a relatively good conducting electrostatic shield around the active part of the detector. This grounded shield provides good protection to E-field environmental events as the induced current is shunted away from the active area and into the system ground. However, magnetic fields pose a more serious problem as the electrostatic shield has very poor magnetic properties.

As such, Hologic has developed guidelines shown below for how to design rooms to minimize the possibility of magnetic interference with the detector. There are many potential sources of EMI interference in a mammography installation and the detector is potentially sensitive to changes in software, hardware, and read out sequences. This combination makes it difficult to specify a single EMI limit that will always work without being unduly restrictive to the installation planning. Although the below guidelines are not quantitative in nature, they define best practices on what to avoid when designing rooms to accommodate a Selenia Dimensions system.

Based on an install base of over 14,000 systems to date, it has been our experience that most sites do not experience EMI related image quality issues. However, some sites have experienced issues which is why Hologic is providing this set of guidelines based on real world experience during thousands of installations. The guidelines are intended to be used in conjunction with the customer requirements to help avoid unnecessary issues during the installation planning process and to help resolve issues if they occur after installation.

For Hologic mammography imaging systems that utilize a digital selenium detector the following statements apply:

- Static EMI fields from sources like the earth's magnetic field and solar activity do not impact image quality.
- Dynamic EMI fields in the range of 60Hz have the most potential to impact image quality.
- Changes in detector software, hardware, firmware, and read out sequences may impact the detector's EMI sensitivity.
- EMI shielding has often proven to be an expensive and ineffective solution to EMI issues.
- Moving the imaging equipment a short distance is often the least expensive and most effective solution to EMI issues.
- We have developed an EMI relative measurement procedure that has proven effective in evaluating potential sources of EMI in an existing installation.

Equipment Placement Guidelines and Considerations

- UPS, Uninterruptable Power Supplies, are known to cause problems. The larger the UPS system, the further away it should be from the image detector. In mobile coaches, the best location for the UPS is at the front of the coach near the driver. In all cases, the UPS or voltage stabilizer external to the system should not be closer than 10 feet (3 meters) from the closest point of the image detector.
- Power rooms containing large electrical panels, switches, or UPS systems should not share a wall, ceiling, or floor with a mammography room.
- AC power lines carrying power for anything other than room convenience outlets should not be directly over, under, or next to gantries. The more current the lines carry, the further away they need to be from the mammography equipment. This includes power lines run on the outside wall of a building.
- Room light dimmers may cause problems.
- DC fluorescent dimming systems in mobile coaches may cause problems.
- When installing at a site containing an MRI system, the Hologic system should not share a wall containing the AC power for the MRI. A good rule of thumb is to have an empty room or hallway between the mammography system and the MRI. The MRI itself will not cause poor image issues, only the AC power supplying the MRI.
- Large electrical loads plugged into convenience outlets, i.e. blanket warmers, copying machines, etc. should not be located near a gantry or on a shared wall in another room. Computers, monitors, and printers typically do not cause problems.
- All circuits need to be well grounded. Each electrical circuit ground should be inspected at the circuit breaker box to make sure the screw is tightened securely to the ground wire.
- Building ground rods should be in good mechanical condition.
- Roof AC service drops should be securely fastened to the pole ground.
- In rooms containing large amounts of structural steel in the walls, i.e. tornado shelters, the customer should ensure that the metal is electrically grounded and not floating.
- Anti-theft screening devices, i.e. Sensormatic devices that use RFID's. These screening devices may be used at entry/exit doorways. These screening devices emit an RF signal that may affect image quality and should not be located near a mammography room.
- When parking a mobile coach to be used for patient examinations do not park near power transmission lines, outdoor transformers, or any other high source of power.

EMI Screening Process

Hologic has developed a two-step screening process that can be used to assess whether a given proposed location will exhibit EMI issues or not when the system is installed. The first step involves screening the location in the sum of X, Y and Z Axes with the F.W. Bell 4180 ELF (Extremely Low Frequency) meter (or equivalent). The specification for the F.W. Bell 4180 ELF meter that is used is shown below.

	Model 4180	Model 4190
Basic Accuracy (> .4 mG, 40-80Hz)	± (2% + 1 digit) typical	± (1% + 1 digit) typical
Frequency Response ±5%	30 to 2kHz	30 to 2kHz
Update Rate (display)	1000 msec single axis, 1200 msec 3- axis mode	
Sampling Rate (Analog Output)	None	8K samples/sec
Measuring Range	0.1 to 599 mG 0.01 to 59.9 µT	0.1 to 1999 mG 0.01 to 199.9 µT
Minimum Resolution	0.1 mG/.01µT	0.1 mG/.01µT
Display	LCD	LCD
Digits	3 1/2	3 1/2
Readings	Gauss, Tesla	Gauss, Tesla
Analog Output	None	2V FS DC or 1V FS AC RMS
Communication Port	USB	USB
Data Logging	No	Yes – Software Data Logging

General Information

Battery Life (Typical)	30 hours
Battery Type	4 AAA Alkaline
Operating Temperature	-10°C to 50°C
External Power Supply	Yes
Weight (with batteries installed)	177 g
Size	4.7" x 3.0" x 1.75" (120 x 76 x 37 mm)

It is important to note that the ELF meter is only sensitive to magnetic fields in the range of 30Hz to 2kHz. While this range covers the range of magnetic field interference generated by AC power lines (60Hz), it is not sensitive to the entire electromagnetic spectrum. The detector, on the other hand, is sensitive to a much broader range of frequencies. Figure 2 (a) and 2(b) below show the relative sensitivity of both the ELF meter and the detector used in Selenia Dimensions as a function frequency.

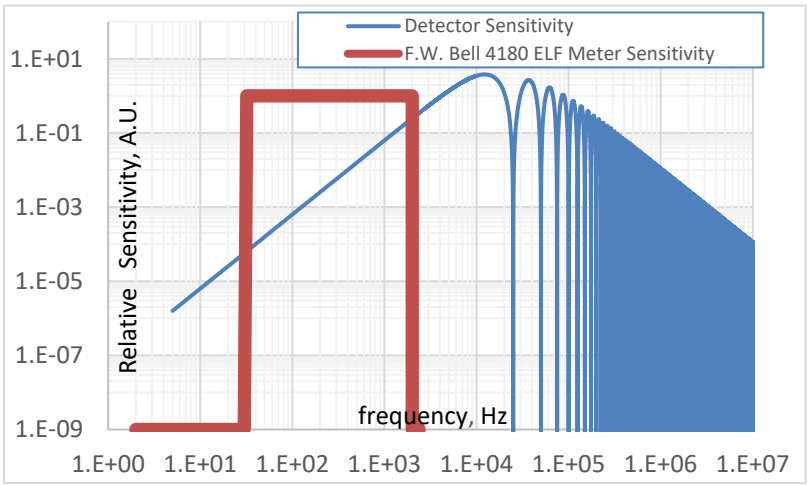

Figure 2 (a)

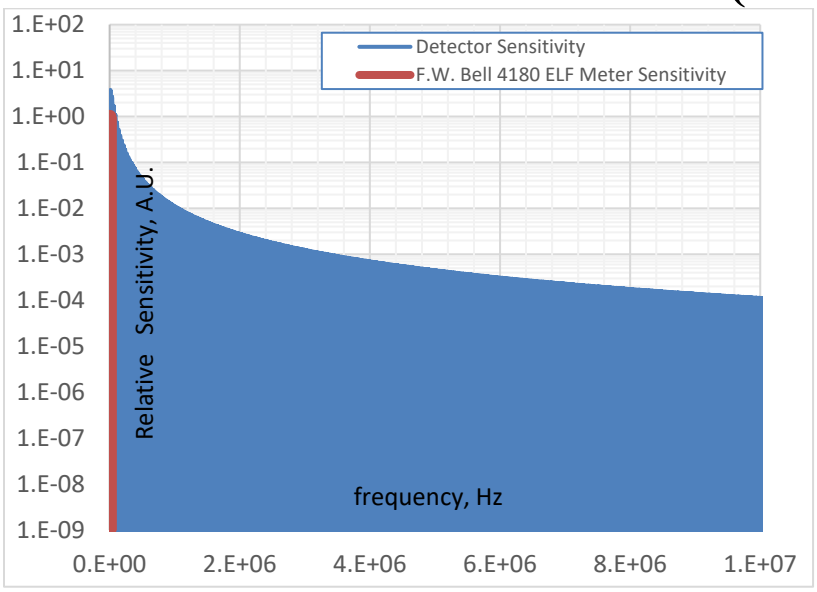

Figure 2(b)

Figure 2 (a) shows the sensitivities on a log plot, whereas Figure 2(b) shows the same sensitivities on a linear plot. As you can see, the range of frequencies that the detector is sensitive to is much broader than the ELF meter and is quite complex in nature. The ELF meter, on the other hand is only sensitive to a very small band of frequencies relative to the detector.

It is Hologic's experience that the majority of field issues related to EMI come from interference with power lines that fall within this narrow range. In fact, using these guidelines, Hologic has screened more than 4,000 sites and 6,700 field installations to date while paying special attention to any abnormal changes over the room background baseline of the magnetic field intensity measured by the ELF meter in the 30Hz-2kHz bandwidth. It is during this analysis that Hologic determines if a secondary measurement is warranted. When the analysis warrants, Hologic uses a proprietary secondary qualitative screening tool (Armadillo) that is sensitive to the same part of the electromagnetic spectrum that the Selenia Dimensions system is susceptible to. It has been found that the two screening tools complement each other, and when used together as explained above, are very effective tools to avoid installation issues related to EMI. This secondary screening method has been utilized on approximately 500 go-no-go investigations of which, less than 25 were identified to have actual EMI issues that could cause an abnormal condition with our detector. While this methodology has been proven to be adequate to uncover most EMI situations prior to install it is not guaranteed that there will not be some type of environmental condition that impacts the detector.

In conclusion if the site guidelines are followed and the room is designed to have an ELF reading < 0.8 milligauss over the 30Hz-2kHz bandwidth with no abnormal variances, it is relatively safe to assume no EMI issues will be present during installation. In many instances, moving the imaging equipment a short distance or to another room is often the least expensive and most effective solution to avoid EMI issues.

DISCLAIMER: THESE GUIDELINES, INCLUDING THE SUGGESTED ELF READING, ARE PROVIDED FOR INFORMATIONAL PURPOSES ONLY. HOLOGIC MAKES NO GUARANTEES WHATSOEVER REGARDING THE POTENTIAL ELECTROMAGNETIC INTERFERENCE WITH HOLOGIC PROUCT PERFORMANCE, WHETHER OR NOT THESE GUIDELINES ARE FOLLOWED.