

CTB-00302 Rev 003

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

Subsystem: Mobile Systems

Subject: Mobile Site Planning and Installation of Selenia Dimensions,
3Dimensions, and Affirm Prone Biopsy Systems

Revision History

Rev 003 – a) Added Purpose, Scope and Instructions sections; b) Added note for approval for changes to step 7 for Hologic Project Manager Responsibilities; c) Added note for coach manufacturer to provide UPS information for use to step 7 under Hologic Field Service Responsibilities; d) Added steps 8 thru 13 for Hologic Field Service Engineer Responsibilities; e) Added step 8 to Coach Manufacturer Responsibilities.

Rev 002 - Added coach manufacturer responsibilities to include moving Hologic equipment in and out of the mobile coach.

Purpose

The purpose of this document is to provide guidance on Mobile Site Planning for Selenia Dimensions, 3Dimensions, and Affirm Prone Biopsy Systems.

Scope

This bulletin is applicable to all mobile Selenia Dimensions, 3Dimensions, and Affirm Prone systems.

Instructions

The following sections list the responsibilities of the Hologic Project Manager, Hologic Field Service Engineer, and Mobile Coach Manufacturer for the planning and installation of a mobile Selenia Dimensions, 3Dimensions, or Affirm Prone system.

Technical Bulletin (cont.)

Hologic Project Manager Responsibilities

The Hologic Project Manager shall provide/review the following with the Coach manufacturer

1. Provide Hologic Mobile Coach Installation guide.
2. Verify that all EMI recommendations have been followed, refer to CTB-00130 EMI Recommendations for Installations.
3. Ensure the customer and the coach manufacturer understand that Hologic does not specify or provide X-Ray shielding for the mobile environment.
4. Review Coach operating environment.
5. Review with coach manufacturer all electrical requirements for the system for shore and mobile power and UPS placement.
6. Review and approve site planning, patient workflow, and service accessibility with coach manufacturer and customer.
7. Provide site plans if requested.

Note: Any changes after review shall require approval between Hologic, the coach manufacturer, and the customer to ensure alignment.

Hologic Field Service Engineer Responsibilities

1. Provide assistance to coach manufacturer with the installation of the new Hologic system.
2. Review site planning, patient workflow and service accessibility with the coach manufacturer.
3. Assist with the cable placement in the coach.
4. Verify that the gantry/table up/down limits will not be obstructed.
5. Ensure the customer and the coach manufacturer understand that Hologic does not specify or provide X-Ray shielding for the mobile environment.
6. Review Coach operating environment.
7. Review with coach manufacturer all electrical requirements for the system for shore and mobile power and UPS placement. The coach manufacturer shall provide UPS configuration/setup information for use.
8. Verify system contents match packing list.
9. Perform EMI surveys with all equipment in the coach operating using shore power and generator power.
10. Install Mobile Kit supplied with system.
11. Perform functional test of gantry and AWS to verify mechanical operation in accordance with service manual.

Technical Bulletin (cont.)

Hologic Field Service Engineer Responsibilities (cont.)

1. Prior to the system leaving the coach manufacturer's facility, the Field Service Engineer shall verify the operation of the gantry's generator. Using generator power, the Field Service Engineer shall perform generator calibrations to ensure proper operation. Calibrations shall be performed with all equipment in the coach operating. (Note: Generator calibrations can be performed without the detector present)

Check kVp Leading Waveform Edge (Adjust if needed)

kVp Verification (Adjust if needed)

Check Standby Voltage (Inverter). Adjust if needed

mA Verification (Adjust if needed)

Filament Calibration – Large and Small

2. The Hologic representative shall obtain from the coach manufacturer information such as UPS setup/configuration, generator/shore power setup, location of breaker(s), and any other features deemed pertinent by both parties where applicable.

Technical Bulletin (cont.)

Coach Manufacturer Responsibilities

1. Review with customer and Project Manager the coach floor plan submitted for weight and balance and safe mobile operation. Work with the Project Manager and customer on changes and /or modifications to equipment placement identified as necessary for safe vehicle operation. Coach manufacturer is responsible for guidance in areas of weight and balance and safe placement of equipment to meet this requirement in his mobile vehicle.
2. Installation of power and mobile power systems (Generator and UPS) including all internal wiring in accordance with local codes (as applicable) to meet Hologic's power specifications for safe and reliable service of the installed Hologic equipment. Securing of the system to the coach shall be performed.
3. Review works in process as necessary with Hologic representative if questions or when changes arise.
4. Ensure an appropriate suspension system is selected for the vehicle that meets or exceeds meeting the vibration limit specifications for the Hologic equipment being installed and assures safe operation.
5. Selection of an appropriate X-Ray shield and fabrication if required. Ensure shielding is adequate according to state or local codes where applicable. Coach manufacturer is responsible for obtaining, specifying, and installing X-Ray shielding in the coach.
6. Consult with Hologic on all changes in placement of UPS devices as these are known to Hologic to generate electrical interference affecting certain digital equipment, always consult on changes to the approved agreed to floor plan.
7. The coach builder is solely responsible for moving Hologic equipment in and out of the coach. Hologic's transportation representatives will deliver and/or pick up equipment from the coach builder's facility only, not from the coach itself.
8. The coach manufacturer shall provide operational information to the Hologic representative on the mobile coach. This shall include items such as UPS setup/configuration, generator/shore power setup, location of breaker(s), and any other features deemed pertinent by both parties where applicable.