

Selenia Dimensions System Label Locations

This addendum changes your Selenia® Dimensions® digital mammography system manuals to update the label locations diagram for systems manufactured after December 2016. Various labels on the Gantry and on the Acquisition Workstation have been consolidated and updated. The following figure shows the new consolidated labels and the labels that they replaced.

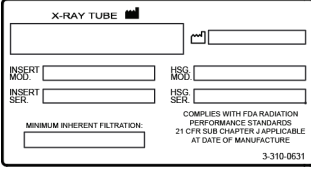
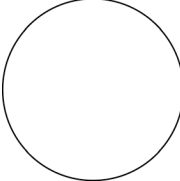
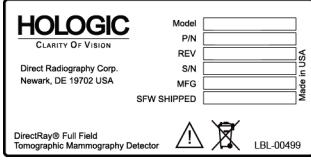
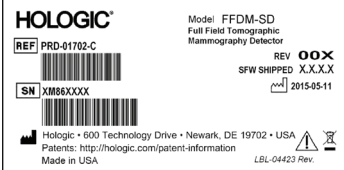
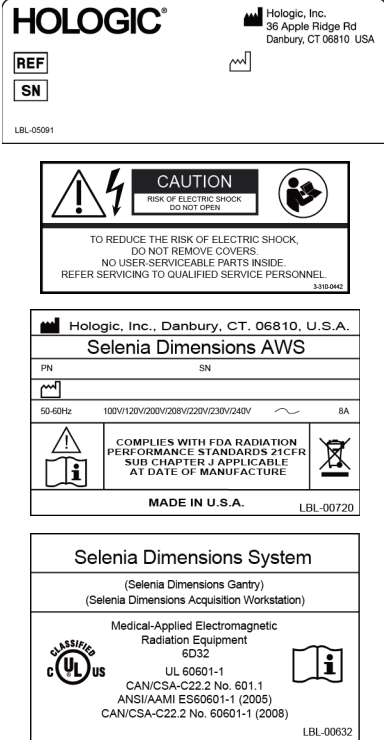

Place this document with your system manuals for future reference.

Label Changes

Table 1: Label Changes (not shown to scale)

| Label Location | Old Label | New Label |
|-------------------|---|---|
| Behind the Gantry | <p>HOLOGIC® Hologic, Inc. 36 Apple Ridge Rd Danbury, CT 06810 USA</p> <p>REF SN</p> <p>LBL-05091</p> <p>Hologic, Inc., Danbury, CT. 06810, U.S.A. Selenia Dimensions System</p> <p>Model: Selenia Dimensions System SN</p> <p>50-60Hz 200V/208V/220V/230V/240V 4A (6SA max. for ≤ 5 sec.)</p> <p>COMPLIES WITH FDA RADIATION PERFORMANCE STANDARDS 21CFR SUB CHAPTER J APPLICABLE AT DATE OF MANUFACTURE.</p> <p>FCC ID: YUJ-PCB00116 IC: 9218A-PCB00116 This device complies with part 15 of the FCC Rules. Operation is subject to the following two conditions: (1) This device may not cause harmful interference, and (2) this device must accept any interference received, including interference that may cause undesired operation.</p> <p>MADE IN U.S.A. LBL-05704</p> <p>This product may be covered by one or more U.S. or foreign patents as identified at: www.hologic.com/patents</p> <p>CE 0044</p> | <p>Hologic, Inc. 36 Apple Ridge Rd. Danbury, CT. 06810, U.S.A. Selenia Dimensions System</p> <p>REF SN</p> <p>50-60Hz 200V/208V/220V/230V/240V 4A (6SA max. for ≤ 5 sec.)</p> <p>COMPLIES WITH FDA RADIATION PERFORMANCE STANDARDS 21CFR SUB CHAPTER J APPLICABLE AT DATE OF MANUFACTURE.</p> <p>FCC ID: YUJ-PCB00116 / IC: 9218A-PCB00116 This device complies with part 15 of the FCC Rules. Operation is subject to the following two conditions: (1) This device may not cause harmful interference, and (2) this device must accept any interference received, including interference that may cause undesired operation.</p> <p>MADE IN U.S.A. LBL-05704 rev.002</p> |
| Behind the Gantry | <p>CAUTION RISK OF ELECTRIC SHOCK DO NOT OPEN</p> <p>TO REDUCE THE RISK OF ELECTRIC SHOCK, DO NOT REMOVE COVERS. NO USER-SERVICEABLE PARTS INSIDE. REFER SERVICING TO QUALIFIED SERVICE PERSONNEL.</p> <p>33180462</p> | <p>CAUTION RISK OF ELECTRIC SHOCK DO NOT OPEN</p> <p>TO REDUCE THE RISK OF ELECTRIC SHOCK, DO NOT REMOVE COVER. NO USER-SERVICEABLE PARTS INSIDE. REFER SERVICING TO QUALIFIED SERVICE PERSONNEL.</p> <p>LBL-05680</p> |

Table 1: Label Changes (not shown to scale)

| Label Location | Old Label | New Label |
|------------------------------------|---|---|
| Behind the Gantry C-arm |  |  <p>(Vendor-supplied X-ray Tube Serial Number Label)</p> |
| Behind the Gantry C-arm |  |  |
| Behind the Acquisition Workstation |  |  |