

El INVIMA informa a los usuarios en general que el Grupo de Tecnovigilancia ha emitido una comunicación relacionada con un Informe de Seguridad asociado a:

NOMBRE DEL DISPOSITIVO MÉDICO	Tomógrafo por Emisión de Fotones
NO. IDENTIFICACIÓN RISARH	I1407-298
REFERENCIAS DEL DISPOSITIVO MEDICO	e.cam y symbia E, referencias y seriales específicos
REGISTRO SANITARIO	2008EBC-0001900
INDICACIONES Y USO ESTABLECIDOS	Sistema de adquisición de imágenes que permite detectar o visualizar la distribución de la absorción de radionúclidos en el cuerpo u órgano, haciendo uso de las siguientes técnicas: tomografía planar, tomografía de cuerpo entero, imagenología topográfica e imagenología para isotopos con energías de hasta 588KeV. Las cabezas de los detectores rotan fácilmente en numerosas posiciones para ofrecer estudios de propósito general, cardiología, oncología y neurología.
NOMBRE DEL FABRICANTE	Siemens Medical Solutions Usa, Inc. Siemens A.G Orbotech Medical Denmark
DESCRIPCION DEL PROBLEMA	El fabricante informa sobre un posible problema por el posible aflojamiento de las ruedas traseras en los carros del colimador, lo que puede conllevar a que se presenten potencialmente retrasos en la realización de los exámenes y atención de los pacientes.
FUENTE	ANEXO 1
FECHA DE NOTIFICACION	18 de Julio de 2014

RECOMENDACIÓN:

En caso de identificar la existencia del producto mencionado anteriormente comuníquese con su proveedor quien determinara las acciones que se llevaran a cabo.

Es importante mantener un estado de alerta, realizando un seguimiento permanente a los productos que se fabrican y/o comercializan en el país, divulgando la información de seguridad respectiva entre los profesionales de la salud que realizan uso de estos recursos tecnológicos.

Para mayor información comuníquese al teléfono 2948700 extensión 3880 en Bogotá, ó al correo electrónico tecnovigilancia@invima.gov.co

ANEXO 1

www.ecri.org • Printed from *Health Devices Alerts* on Friday, July 18, 2014 Page 1

A22695 - High Priority Medical Device Alert

**Medical Device
Ongoing Action**

Updated: July 17, 2014

UMDNS Terms:

- Scanning Systems,
Gamma Camera,
Single Photon
Emission Tomography
[18444]

Suggested Distribution:

- Clinical/Biomedical
Engineering
- Diagnostic Imaging
- Nuclear Medicine

Geographic Regions:

- (Impact in specific
regions has not been
identified or ruled out at
the time of this posting)
- Worldwide

**Siemens—Collimeter Carts Used with e.cam and Symbia
E Series Single-Photon Emission Computed Tomography
Systems: Rear Casters May Become Loose**

Product Identifier:

Collimeter Carts used with the following e.cam and Symbia E Series Single-Photon Emission Computed Tomograph (SPECT) Systems:	Model Nos.:	Serial Nos.:
e.cam DCR Duet Head A (e.soft)	5989095	7504, 8021, 8504, 8505
e.cam DCR Gantry Dual Head, B	7823920	3097, 8505, 8506, 8513, 8515, 8517, 8518, 8519, 8520, 8522

e.cam DCR Gantry Single Head	5989087	8538
e.cam DCR Gantry Single Head, B	7823938	2011, 5504, 7510, 8509, 8518, 8520
e.cam Dual Head (ICON S)	4380221	1012, 1022, 1023, 1037, 1091, 1099, 1127, 1145, 1150, 1151, 1174, 1187, 1191, 1201, 1211, 5090

		1019, 1020, 1024, 1042, 1068, 1070, 1081, 1089, 1090, 1095, 1112, 1129, 1130, 1131, 1135, 1136, 1137, 1138, 1139, 1141, 1142, 1143, 2016, 2017, 2019, 2048, 2062, 2099, 2107, 2111, 2118, 2119, 2120, 2122, 2124, 2125, 2127, 2128, 3003, 3011, 3015, 3024, 3029, 3031, 3034, 3050, 3070, 3111, 3135, 3137, 3139, 4035, 4042, 4078
e.cam Duet Head (e.soft)	5984005	7501, 7509
e.cam Extended Gantry Dual Head v3	5991109	5505, 5518, 5521, 5523, 5527, 5531, 5537, 5551, 5559, 5562, 5573, 5575, 5580, 5581, 5595, 5596, 5671, 5672, 5673, 5674, 5675, 5676, 5677, 5678, 5679, 7030, 7036, 7044, 7102, 7503, 7507, 7515, 7517, 7519, 7520, 7525, 7529, 7551, 7555, 7560
e.cam Extended Gantry Single Head	5991117	5515

e.cam Gantry Dual H ead v3.0Int	5992099	5101, 5142, 5159, 5167, 5169
e.cam Gantry Dual Head v2.5	5977066	4107, 4114, 4122, 4125, 4136, 4167, 4183, 4186, 5007, 5033, 5034, 5038, 5046, 5117, 6001, 7503

e.cam Gantry Dual Head v3.7	5989079	7519, 7522, 7523, 7527, 7542, 7553, 7558, 7563, 7567, 7576, 7587, 7589, 7590, 7592, 7593, 7600, 7602, 7605, 7610, 7611, 7620, 7626, 7651, 8020, 8021, 8022, 8025, 8040, 8042, 8060, 8063, 8067, 8106, 8119, 8133, 8138, 8520, 8531, 8534, 8559, 8596, 8600, 8607, 8630, 8631, 8641, 8657, 8666, 8675, 8681, 8685, 8726, 8736, 8737, 8740, 8741, 8747, 8754, 8757, 8761, 8769, 8771, 8773, 8782, 8783, 8784, 8786, 8790, 8791, 8793, 8806, 8815, 8819, 8822, 8829, 8833, 8835, 8837, 8838, 8839, 8841, 8842, 71101, 71102
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e.cam Gantry Foresight Sign_Ser 1Hd	10151531	1002, 1003, 1004, 1005, 1006, 1007, 1009, 1010, 1011, 1012, 1013, 1014, 1015, 1016, 1017, 1019, 1020, 1021, 1022, 1023, 1024, 1025, 1026, 1027, 1028, 1029, 1030, 1031, 1032, 1033, 1034, 1035, 1036, 1037, 1038, 1039, 1041, 1042, 1043, 1046, 1047, 1048, 1049, 1050, 1051, 1052, 1053, 1054, 1055, 1056, 1057, 1058, 1059, 1060, 1061, 1062, 1063, 1064, 1065, 1066, 1068, 1069, 1070, 1071, 1072, 1073, 1074, 1075, 1076, 1077, 1078, 1079, 1080, 1081, 1082, 1083, 1084, 1085, 11131, 70001, 70002, 70003
e.cam Gantry Single Head v3.0	5977074	4044
e.cam Single Head (ICON S)	4380213	1012, 1018, 2005, 2018, 3004, 3027, 3028

e.cam Single Special Configuration	10520745	9995
Signature e.cam Dual Camera, A	7760932	8191, 8501, 8502, 8503, 8506, 8507, 8508, 8509, 8510, 8511, 8512, 8513, 8514, 8515, 8516, 8517, 8518, 8519, 8520, 8521, 8522, 8523, 8524, 8526, 8527, 8529, 8530, 8531, 8532, 8533, 8534, 8535, 8536, 8537, 8538, 8539, 8539, 8540, 8541, 8542, 8543, 8544, 8545, 8546, 8547, 8548, 8549, 8550, 8551, 8552, 8553, 8554, 8555, 8556, 8557, 8558, 8560, 8561, 8562, 8563, 8564, 8565, 8566, 8567, 8568, 8569, 8570, 8571, 8572, 8573, 8574, 8575, 8576, 8577, 8578, 8579, 8580, 8581, 8582, 8583, 9001, 9003, 9004, 9005, 9007, 9008, 9010, 9011, 9012, 9013, 9014, 9015, 9017, 9018, 9019, 9020, 9021, 9022, 9023, 9024, 9027, 9028, 9029, 9030, 9031, 9032, 9033, 9034, 9036, 9037, 9038, 9039, 9041, 9043, 9044

Signature e.cam Dual Camera, B	7823946	5382, 5389, 5517, 5764, 6481, 8490, 9001, 9002, 9003, 9004, 9005, 9006, 9007, 9008, 9009, 9010, 9011, 9013, 9014, 9015, 9016, 9017, 9018, 9019, 9020, 9021, 9022, 9023, 9024, 9025, 9027, 9028, 9029, 9030, 9031, 9033, 9034, 9035, 9036, 9037, 9039, 9040, 9041, 9043, 9044, 9045, 9046, 9047, 9048, 9049, 9050, 9051, 9052, 9053, 9054, 9055, 9056, 9057, 9058, 9059, 9060, 9061, 9062, 9063, 9064, 9065, 9066, 9067, 9068, 9069, 9070, 9071, 9072, 9073, 9074, 9075, 9076, 9077, 9078, 9079, 9080, 9081, 9082, 9083, 9084, 9085, 9086, 9087, 9088, 9089, 9090, 9091, 9092, 9093, 9094, 9095, 9096, 9097, 9098, 9099, 9100, 9101, 9102, 9103, 9104, 9105, 9106, 9107, 9109, 9110, 9111, 9112, 9113, 9115, 9116, 9117, 9118, 9122, 9123, 9124, 9125, 9126, 9127, 9128, 9129, 9130, 9131, 9132, 9133, 9134, 9135, 9136, 9137, 9138, 9141, 9142, 9143, 9144, 9145, 9146, 9147, 9148, 9149, 9150, 9151, 9152, 9153, 9154, 9155, 9156, 9157, 9158, 9160, 9161, 9162, 9163, 9164, 9165, 9166, 9167, 9168, 9169, 9170, 9171, 9172, 9173, 9174, 9175, 9176, 9177, 9179, 9180, 9182, 9183, 9184, 9185, 9187, 9188, 9189, 9190, 9191, 9192, 9193, 9194, 9195, 9197, 9198, 9199, 9200, 9201, 9202, 9203, 9204, 9205, 9206, 9207, 9208, 9209, 9210, 9211, 9212, 9213, 9214, 9215, 9216, 9217, 9219, 9220, 9221, 9222, 9223, 9224, 9226, 9227, 9228, 9229, 9230, 9231, 9232, 9233, 9234, 9235, 9236, 9237, 9238, 9239, 9240, 9241, 9242, 9243, 9245, 9246, 9247, 9248, 9249, 9250, 9251, 9252, 9253, 9254, 9254, 9255, 9256, 9257, 9259, 9260, 9261, 9262, 9263, 9264, 9265, 9266, 9267, 9268, 9269, 9270, 9271, 9272, 9273, 9274,
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Signature e.cam Duet Camera, A	7761161	8501, 8502, 8503

Signature e.cam Duet Camera, B	7823979	6324, 6683, 9001, 9004, 9005, 9007, 9009, 9010, 9012, 9015, 9017, 9018, 9019, 9020, 9021, 9023, 9025, 9026, 9028, 9029, 9031, 9304
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<p>Signature e.cam Single Camera, B</p>	<p>8502, 8503, 8504, 8505, 8506, 8507, 8509, 9001, 9002, 9003, 9004, 9005, 9006, 9007, 9008, 9009, 9010, 9011, 9012, 9013, 9015, 9016, 9017, 9018, 9019, 9020, 9021, 9022, 9023, 9024, 9025, 9026, 9027, 9028, 9029, 9030, 9032, 9033, 9034, 9035, 9036, 9037, 9038, 9040, 9041, 9042, 9043, 9044, 9045, 9658, 10000, 10001, 10002, 10003, 10004, 10005, 10007, 10008, 10009, 10010, 10011, 10012, 10013, 10014, 10015, 10016, 10017, 10018, 10019, 10020, 10022, 10023, 10024, 10025, 10026, 10027, 10028, 10029, 10030, 10031, 10032, 10033, 10034, 10035, 10036, 10037, 10038, 10039, 10040, 10041, 10042, 10043, 10044, 10045, 10046, 10047, 10049, 10050, 10051, 10052, 10053, 10054, 10055, 10056, 10057, 10058, 10059, 10060, 10061, 10062, 10063, 10064, 11001, 11002, 11003, 11004, 11005, 11006, 11007, 11008, 11009, 11010, 11011, 11012, 11013, 11014, 11015, 11016, 11017, 11018, 11019, 11020, 11021, 11022, 11023, 11024, 11025, 11026, 11028, 11029, 11030, 11031, 11032, 11033, 11034, 11035, 11036, 11037, 11038, 11039, 11040, 11041, 11042, 11044, 11045, 11046, 11048, 11049, 11050, 11052, 11053, 11054, 11055, 11056, 11057, 11058, 11059, 11060, 11061, 11063, 11064, 11065, 11066, 11067, 11068, 11069, 11070, 11071, 11072, 11073, 11074, 11075, 11076, 11077, 11078, 11079, 11080, 11081, 11082, 11083, 11084, 11086, 11088, 11089, 11090, 11091, 11092, 11093, 11095, 11096, 11097, 11098, 11099, 11100, 11101, 11102, 11103, 11104,</p>
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Signature e.cam Single Cameral, A	7760809	8501, 8502, 8503, 8504, 8505, 8506, 8507, 8508, 8509, 8510

<p>Signature Foresight e.cam Dual Camera</p>	<p>1001, 1003, 1004, 1005, 1006, 1008, 1009, 1010, 1013, 1014, 1015, 1016, 1017, 1018, 1019, 1021, 1022, 1023, 1024, 1025, 1026, 1027, 1028, 1029, 1030, 1031, 1032, 1033, 1034, 1036, 1037, 1038, 1040, 1041, 1042, 1043, 1044, 1045, 1047, 1048, 1049, 1050, 1051, 1052, 1053, 1054, 1055, 1056, 1057, 1058, 1059, 1060, 1061, 1064, 1065, 1066, 1067, 1068, 1069, 1070, 1071, 1072, 1073, 1074, 1075, 1076, 1079, 1080, 1081, 1082, 1083, 1084, 1085, 1086, 1088, 1090, 1091, 1092, 1094, 1095, 1096, 1097, 1098, 1099, 1100, 1101, 1102, 1103, 1104, 1105, 1106, 1107, 1108, 1109, 1110, 1111, 1112, 1113, 1114, 1115, 1116, 1117, 1118, 1119, 1120, 1122, 1123, 1124, 1125, 1126, 1127, 1128, 1129, 1130, 1131, 1132, 1133, 1134, 1135, 1136, 1137, 1138, 1139, 1140, 1141, 1142, 1143, 1144, 1145, 1146, 1147, 1148, 1149, 1150, 1151, 1152, 1153, 1154, 1155, 1156, 1157, 1158, 1159, 1160, 1161, 1162, 1163, 1164, 1165, 1166, 1167, 1168, 1169, 1170, 1172, 1173, 1174, 1177, 1178, 1179, 1180, 1181, 1182, 1183, 1184, 1185, 1186, 1187, 1188, 1189, 1190, 1191, 1192, 1193, 1194, 1195, 1196, 1198, 1199, 1200, 1201, 1202, 1203, 1204, 1205, 1206, 1207, 1208, 1209, 1210, 1211, 1212, 1213, 1214, 1217, 1218, 1219, 1220, 1221, 1222, 1223, 1224, 1225, 1226, 1227, 1228, 1229, 1230, 1231, 1232, 1233, 1234, 1235, 1236, 1237, 1238, 1239, 1240, 1241, 1242, 1243, 1244, 1245, 1246, 1247, 1248, 1249, 1250, 1251, 1252, 1253, 1255, 1256, 1257, 1258, 1259, 1261, 1263, 1264, 1265, 1266, 1267, 1268, 1270, 1271, 1272, 1273, 1274, 1275, 1279, 1280, 1281, 1282, 1284, 1285, 1286, 1287, 1288, 1289, 1290,</p>
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Symbia E Dual Head	<p>1001, 1002, 1003, 1004, 1005, 1007, 1010, 1011, 1012, 1013, 1014, 1015, 1016, 1017, 1018, 1019, 1020, 1021, 1022, 1023, 1024, 1025, 1026, 1027, 1028, 1029, 1030, 1031, 1032, 1034, 1035, 1036, 1037, 1038, 1039, 1040, 1041, 1042, 1043, 1044, 1045, 1046, 1047, 1048, 1049, 1050, 1051, 1052, 1053, 1054, 1055, 1056, 1057, 1058, 1059, 1060, 1061, 1062, 1063, 1064, 1065, 1066, 1067, 1068, 1069, 1070, 1071, 1072, 1073, 1074, 1075, 1076, 1077, 1078, 1079, 1080, 1081, 1082, 1083, 1084, 1085, 1086, 1087, 1088, 1089, 1090, 1091, 1092, 1093, 1094, 1095, 1096, 1097, 1098, 1099, 1100, 1101, 1102, 1103, 1104, 1105, 1106, 1107, 1108, 1109, 1110, 1111, 1112, 1113, 1114, 1115, 1116, 1117, 1118, 1119, 1120, 1121, 1122, 1123, 1124, 1125, 1126, 1127, 1128, 1129, 1130, 1131, 1132, 1133, 1134, 1135, 1136, 1137, 1138, 1139, 1140, 1141, 1142, 1143, 1144, 1145, 1146, 1147, 1148, 1149, 1150, 1151, 1152, 1153, 1154, 1155, 1156, 1157, 1158, 1159, 1160, 1161, 1162, 1163, 1165, 1166, 1167, 1168, 1169, 1170, 1171, 1172, 1173, 1174, 1175, 1176, 1177, 1178, 1179, 1180, 1181, 1182, 1183, 1184, 1185, 1186, 1189, 1190, 1191, 1192, 1193, 1194, 1195, 1196, 1197, 1198, 1199, 1200, 1201, 1202, 1203, 1205, 1206, 1207, 1208, 1209, 1210, 1211, 1212, 1213, 1214, 1215, 1216, 1217, 1218, 1219, 1220, 1221, 1222, 1223, 1224, 1225, 1226, 1227, 1228, 1229, 1230, 1231, 1232, 1233, 1234, 1235, 1236, 1237, 1238, 1239, 1240, 1241, 1242, 1243, 1244, 1245, 1246, 1247, 1248, 1249, 1250, 1251, 1252, 1253, 1254, 1255, 1256, 1257, 1258, 1259, 1260, 1261, 1262, 1263, 1264, 1265, 1266, 1267, 1268,</p>
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Symbia E Single Head	10413009	1001, 1002, 1003, 1004, 1006, 1007, 1009, 1010, 1011, 1013, 1014, 1015, 1017, 1018, 1019, 1020, 1021, 1022, 1023, 1024, 1025, 1026, 1027, 1028, 1029, 1030, 1031, 1032, 1033, 1034, 1035, 1036, 1037, 1038, 1039, 1040, 1041, 1042, 1043, 1044, 1045, 1046, 1047
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[Capital Equipment]

Manufacturer:

- Siemens Medical Solutions USA Inc2501 N Barrington Rd, Hoffman Estates, IL 60192, United States

Problem: FDA's Center for Devices and Radiological Health (CDRH) states that the rear casters on the collimator carts of the above systems may become loose. FDA's CDRH also states that the manufacturer initiated a product correction by Customer Safety Advisory Notice letter dated April 23, 2014. The manufacturer has not confirmed the information provided in the source material.

Action Needed:

Identify and discontinue use of any affected carts in your inventory. If you have affected product, verify that you have received the April 23, 2014, Customer Safety Advisory Notice letter from Siemens. Notify your local service representative if you observe or suspect that one or more casters are loose (indicated by shaking while the cart is in motion). A Siemens service representative will contact your facility to schedule a retention bracket installation.

For Further Information:

Siemens

Tel.: (800) 888-7436

Website: [Click here](#)

References:

United States:

- Food and Drug Administration. Center for Devices and Radiological Health. Class 2 device recall E.CAM [online]. 2014 Jul 11 [cited 2014 Jul 15]. Available from Internet: [Click here](#).
- Food and Drug Administration. Center for Devices and Radiological Health. Class 2 device recall Symbia E [online]. 2014 Jul 11 [cited 2014 Jul 15]. Available from Internet: [Click here](#).

Comment:

- This alert is a living document and may be updated when ECRI Institute receives additional information. In circumstances in which we determine that it is appropriate for customers to repeat their review of an issue (e.g., when additional affected product has been identified), we will post a separate update alert. In other cases, we may add information, such as additional commentary, recommendations, and/or source documents, to the original alert. For additional information regarding the format of this alert, refer to our [HDA Format Guide](#).

Source(s):

- 2014 Jul 15. FDA CDRH Database. Class II. Z-2042/2043-2014