

## 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:

<b>NOMBRE DEL DISPOSITIVO MÉDICO</b>	Equipo Híbrido SPECT-CT SIEMENS
<b>NO. IDENTIFICACIÓN RISARH</b>	I1501-44
<b>REFERENCIAS DEL DISPOSITIVO MÉDICO</b>	SYMBIA T y SYMBIA T2
<b>REGISTRO SANITARIO</b>	2008EBC-0002090
<b>INDICACIONES Y USO ESTABLECIDOS</b>	Sistema de adquisición de imágenes que realiza un estudio mediante la fusión de tomografía computarizada e imagenología nuclear.
<b>NOMBRE DEL FABRICANTE</b>	Siemens A.G
<b>DESCRIPCION DEL PROBLEMA</b>	El fabricante afirma que un componente con número de parte 10275007 y 10275008 respectivamente dentro de los sistemas de CT anteriores, puede aflojarse y dañar el sistema, conllevando a que se presenten posibles eventos adversos sobre los pacientes.
<b>FUENTE</b>	ANEXO 1
<b>FECHA DE NOTIFICACION</b>	23 de Enero de 2015

### 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](mailto:tecnovigilancia@invima.gov.co)

## ANEXO 1

www.ecri.org . Printed from *Health Devices Alerts* on Friday, January 23, 2015 Page 1

### [Normal Priority] - A23699 : Siemens—Symbia T and Symbia T2 SPECT/CT Systems: Component May Become Loose and Damage the System Medical Device Ongoing Action

#### UMDNS Terms:

- Scanning Systems, Computed Tomography/Single Photon Computed Tomography [24013]

#### Product Identifier:

Single Photon Computed Tomography/Computer Tomography (SPECT) Systems:	Part No.:	Serial Nos.:
Symbia T	10275007	1055, 1057, 1058, 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, 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, 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, 1164, 1165, 1166, 1167, 1168, 1169, 1170, 1171, 1172, 1173, 1175, 1176, 1177, 1178, 1179, 1180, 1181, 1182, 1183, 1184, 1185, 1186, 1187, 1188, 1189, 1190, 1191, 1193, 1194, 1195, 1196, 1197, 1198, 1199, 1200, 1201, 1202, 1203, 1204, 1205, 1206, 1207, 1208, 1209, 1210, 1211, 1212, 1214, 1215, 1216, 1217, 1218, 1219, 1220, 1221, 1222, 1223, 1024, 1025, 1026, 1039, 1040, 1049, 1050, 1054, 1055, 1056, 1054, 1055, 1056, 1060, 1069, 1040, 1041, 1042, 1043, 1044, 1045, 1046, 1049, 1048, 1050, 1059, 1060, 1081, 1082, 1083, 1085, 1086, 1087, 1088, 1089, 1090, 1091, 1092, 1094, 1095, 1096, 1097, 1098, 1099, 1100, 1101, 1102, 1103, 1104, 1107, 1108, 1109, 1110, 1111, 1113, 1114, 1115, 1116, 1117, 1118, 1119, 1120, 1121, 1122, 1123, 1125, 1126, 1127, 1128, 1129, 1130, 1131, 1132, 1133, 1135, 1136, 1137, 1138, 1139, 1140, 1141, 1142, 1143, 1144, 1145, 1147, 1148, 1149, 1150, 1151, 1152, 1153, 1154, 1155, 1156, 1157, 1158, 1159, 1160, 1161, 1162, 1163, 1164, 1165, 1166, 1167, 1168, 1169, 1170, 1171, 1172, 1173, 1175, 1176, 1182, 1183, 1184, 1185, 1186, 1187, 1188, 1189, 1190, 1191, 1193, 1194, 1195, 1196, 1197, 1198, 1199, 1200, 1201, 1202, 1203, 1204, 1205, 1206, 1207, 1208, 1209, 1210, 1211, 1212, 1214, 1215, 1216, 1217, 1218, 1219, 1220, 1221, 1222, 1223, 1162, 1164, 1166, 1167, 1168, 1169, 1566
		Symbia T2

[Capital Equipment]  
295 units distributed

**Geographic Regions:** Worldwide

**Manufacturer(s):** Siemens Healthcare 51 Valley Stream Pkwy, Malvern, PA 19355, United States

**Suggested Distribution:** Clinical/Biomedical Engineering, Diagnostic Imaging, Nuclear Medicine

#### Problem:

FDA's Center for Devices and Radiological Health (CDRH) states that a component inside the above CT systems may become loose and damage the system. FDA's CDRH also states that Siemens initiated a correction by Customer Safety Advisory Notice letter. The manufacturer states that the recall was initiated in 2014 and is nearly complete worldwide.

**Action Needed:** Identify any affected product in your inventory. If you have affected product, verify that you have received the Customer Safety Advisory Notice letter from Siemens. Siemens states that you can continue to use your system until inspections are performed. Retain a copy of the letter with the system's instructions for use. Notify all relevant personnel at your facility of the information in the letter. Forward a copy of the letter to any facility to which you have further distributed affected product.

#### For Further Information:

Siemens  
Tel.: (800) 888-7436 (U.S.)  
Website: [Click here](#)

#### References:

- United States. Food and Drug Administration. Center for Devices and Radiological Health. Class 2 device recall Symbia T and Symbia T2 [online]. 2015 Jan 13 [cited 2015 Jan 16]. Available from Internet: [Click here](#).

#### Comments:

- 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):

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- 2015 Jan 16. FDA CDRH Database. Class II. Z-0960-2015 [Download](#)
- 2015 Jan 19. Manufacturer. Manufacturer confirmed information.